



The Pharmaceutical Market in Greece | **FACTS & FIGURES** | **2017**



FOUNDATION
FOR ECONOMIC &
INDUSTRIAL RESEARCH



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The report “**The Pharmaceutical Market in Greece: Facts & Figures 2017**” was produced by Health Economics Observatory research staff of IOBE with the cooperation of SfEE’s Data Monitoring Committee.

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FOREWORD -ACKNOWLEDGMENTS

“The Pharmaceutical Market in Greece: Facts & Figures 2017”

It is with great pleasure to preface the renewed annual edition ‘**The Pharmaceutical Market in Greece: Facts & Figures 2017**’, produced by research staff of IOBE in collaboration with SfEE’s Data Monitoring Committee.

As it has been established during the past years from our association, this report intends to provide **the most comprehensive overview of key facts and data of the pharmaceutical market in Greece**, in order to inform both our members and other stakeholders in the broader health sector.

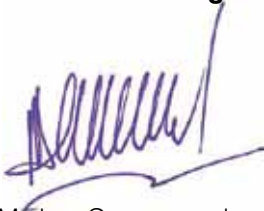
More specifically, this year’s edition covers the most important **social and economic changes from the long recessionary period in our country**, and records the impact of **fiscal adjustment on health** and specifically on **pharmaceutical sector**, through comparison with other European Union countries, and with Southern countries implemented similar economic adjustment programs.

This edition attempted to include all data available until the end of 2017, in order to present an **updated profile of the pharmaceutical market** and the main changes that occurred.

At a particularly important point for our country, when strategic planning and vision to shape national health policy are required, evidence based decisions should be the primary focus of all stakeholders; in this context, this report aims to demonstrate the added value of pharmaceutical sector for the Greek economy.

We would like to thank the IOBE research staff and the members of SfEE Data Monitoring Committee.

President of Data Monitoring Committee



Markos Gerassopoulos
General Secretary

For SfEE



Pascal Apostolides
President

EXECUTIVE SUMMARY

During 2010-2017, Greece implemented a major economic adjustment program, that resulted into a deep and continuous recession for the Greek economy. The most important consequences of the economic adjustment program for 2016, was the **decrease in GDP** (cumulative loss of -26.4% from 2007), **unemployment** at 23.6% of total population, especially profound in the youth population of 15-24 years old (47.3%), and **poverty risk** at 36% of total population. The consequences of the above, are reflected amongst others, on the dependency ratio with nearly half of the population dependent on the other half, a proportion expected to grow in the future.

The above socioeconomic factors significantly affected the health care sector in Greece. **Total health expenditure** decreased by -32.4% during 2010-2016 (-0.6% in Southern countries, +11.8% in EU) and amounted to €14.6 bil. in 2016 (8.3% of GDP), while **public health expenditure** decreased by -42.5% (-5.7% in Southern countries, +10.1% in EU) the same period, and amounted to €8.5 bil. in 2016 (4.8% of GDP). The reduction in public funding resulted in a shift towards private, with **private health expenditure** at 40.9% of the total health expenditure in 2016 (27% in Southern countries, 21% in EU)

However, the needs of the population for health care are affected, amongst others, by demographic trends: **life expectancy** in Greece is high (81.1 years close to EU average in 2015), **steady reduction of the population** (births - deaths) by -26,000 people (2016), and **increased aging population** (over 65) from 21.6% of the total population in 2017 rising to 36.5% in 2050.

From the above, the growing demand for health care, thus for public funding on health care services and pharmaceuticals is documented, with further increase in the private expenditure considered unsustainable in an environment of long-term unemployment and significant decline of national income.

With regards to the pharmaceutical expenditure, which is a small part of total health expenditure (~15%), **total outpatient pharmaceutical expenditure** in Greece estimated at ~€3.7 bil. in 2017, (€1,945 bil. is public pharmaceutical expenditure) close to 2012 levels, while during the same period **public outpatient pharmaceutical expenditure** decreased by -32%. The significant decline of public funding, resulted in a shift towards private sector, with the **estimated patients' contribution** (copayment) at ~25% and **industry's contribution**, through flat mandatory returns and discounts (rebate and clawback), accounting for the rest ~25% (€902 mil.).

On the other side, **hospital (inpatient) pharmaceutical expenditure** estimated at ~€760 mil. on average during 2012-2015. From 2016 onwards, with the introduction of closed budget, **public hospital pharmaceutical expenditure** decreased significantly, while in 2018 is expected to reach €530 mil. (-30% compared to 2015). Therefore, the reduction of public hospital pharmaceutical expenditure shifted exclusively to the **industry**, through flat mandatory returns and discounts (rebate and clawback), estimated at €260 mil. and €320 mil. for 2016 and 2017, respectively.


Despite the significant impact of fiscal adjustment on public funding, the pharmaceutical industry remains a **pillar for investment** in Greece with **2,265 clinical studies** independent of phase and stage until 2017 and **Research and Development (R&D) expenditure** close to 12% of total R&D expenditure in Greece (2013). **Production of pharmaceutical products in Greece** was estimated at €948 mil., with Gross Value Added (ex-factory) at €624 mil. (3.4% of the manufacturing), and ranks 9th amongst 24 other manufacturing sectors on a national level. **Employment in the manufacturing of pharmaceutical products in Greece** was estimated at 15.5 thousand people in the first half of 2017, with 64% of them with **university education**, compared to 35% of the total manufacturing and 22.7% of the total economy.

Imports and exports of medicinal products amounted to €2.9 bil. and €1.0 bil., respectively in 2016. Lastly, exports accounted for 4.2% of total Greek exports in 2016.

KEY STATISTICS OF GREEK PHARMACEUTICAL MARKET

DEMOGRAPHICS

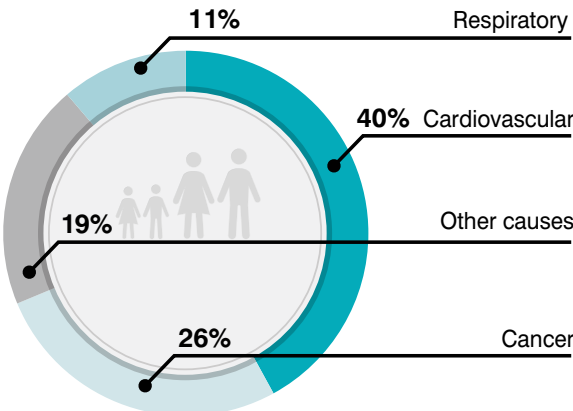
“ New innovative therapies contributed to the increase of life expectancy, however the steady decline of Greek population since 2011, and the increase of the population 65+ years old, age group suffering from chronic diseases, pose a significant burden and challenge the sustainability of the health care system. ”

	Greece	Southern countries	EU28
 Life expectancy (years) 2015	81.1	82.6	81.1*
 Births - deaths (per 1,000 people)+ 2015	-2.7	-1.6	-0.3
 Population > 65 years (%) 2020	22.6%	21.8%	20.4%

SOURCE: OECD, Health Statistics 2017, Southern countries (Italy, Spain, Portugal), data processing IOBE, EL.STAT. 2016 provisional data Eurostat, Population Projections 2017, not including possible legalization of migration from 2015 onwards, *EU22, +Weighted with the population per 1,000 people.

Causes of death in Greece

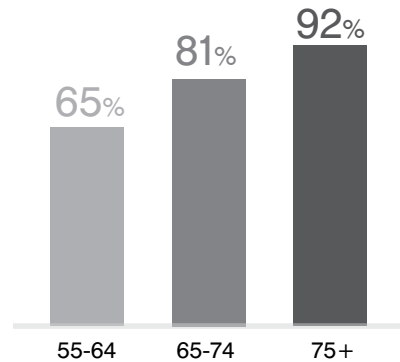
(% of total deaths, 2014)



Population with chronic disease

(% on population per age group, 2014)

“ ~ 4.5 mil. people suffer from a chronic disease, out of which 62% are above 55 years old ”

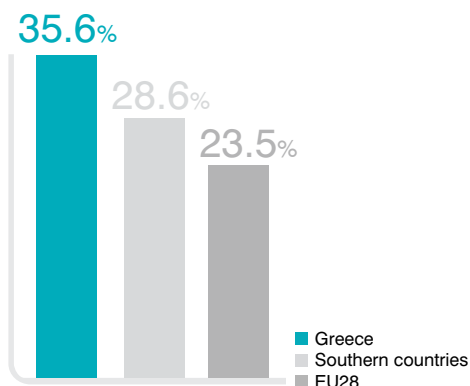


SOURCE: EL.STAT. 2016, Health Survey 2014, data processing IOBE, Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations. Other causes: Diseases of the digestive system, Diseases of the genitourinary system, Diseases of the nervous system and sense organs, Endocrine and metabolic diseases, nutritional deficiencies and immune disorders.

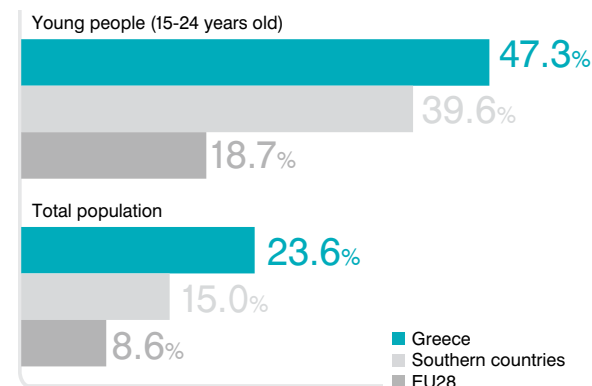
SOCIAL INDICATORS

“ The impact of the deep recession on the Greek economy is reflected in the high unemployment rate, more profound on young people - almost half out of the labour market - composing the most productive age group, resulting in brain drain. At the same time, the significant reduction of the national income, has led to poverty risk for 35 out of 100 Greeks. ”

Poverty risk (%) 2016



Unemployment (%) 2016

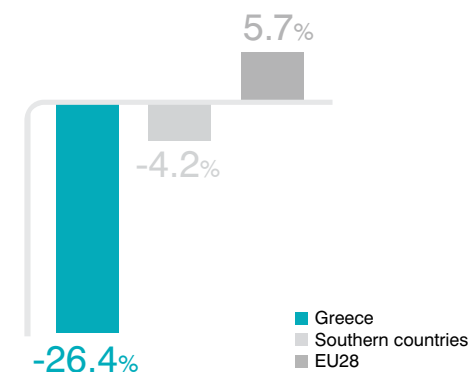


SOURCE: Eurostat, 2017, European Commission, Spring 2017 Economic Forecast, data processing IOBE, Southern countries (Italy, Spain, Portugal), Percentage of people at poverty risk: percentage of people with disposable income below 60% of the national median income. Median income is the income above which is the 50% of the population.

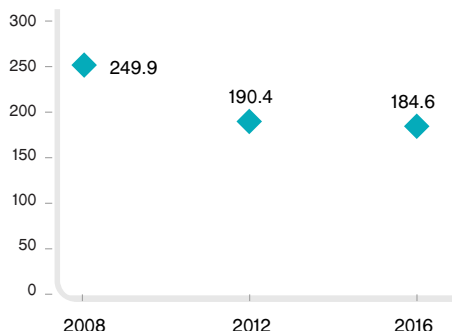
ECONOMIC INDICATORS

“ The Greek economy has experienced a persistent recession, as a major and intense economic adjustment program has been implemented after 2010, with a reduction of public spending and taxation increase, that resulted in significant reduction of GDP, with a cumulative GDP change in 2016 standing at 73.6%, that is cumulative loss of -26.4%. GDP amounted at €184.6 bil. (2016), slightly decreased by -0.2% compared to 2015, with a recovery expected in 2017 on a growth rate of 1.6%. ”

Cumulative GDP change (2016 with baseline 2007)



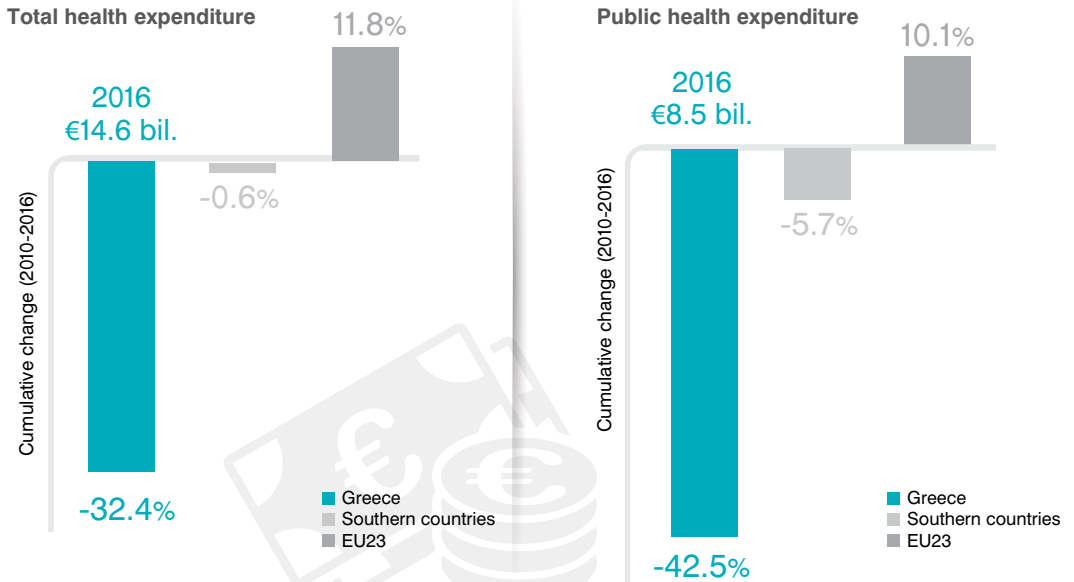
Evolution of GDP in Greece (bil. €)



SOURCE: Eurostat 2017, AMECO 2017 (Autumn 2017 Economic Forecast), GDP Chain linked volumes 2010, data processing IOBE, Southern countries (Italy, Spain, Portugal), IOBE: The Greek Economy, 3rd quarter 2017.

HEALTH EXPENDITURE

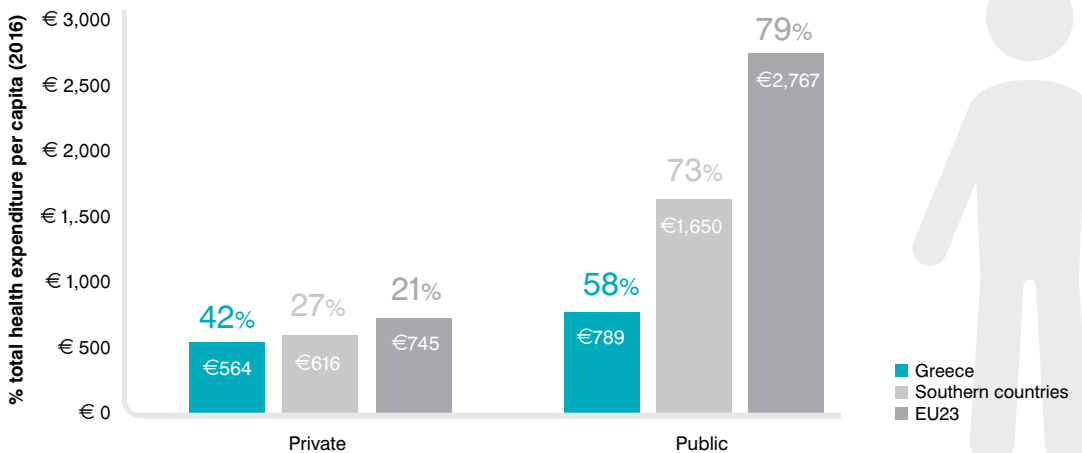
“ During fiscal adjustment period in Greece, a significant decline of total health expenditure by -32.4% is recorded, with a higher decline of public health expenditure by -42.5%. ”



SOURCE: System of Health Accounts (SHA) 2015, OECD Health Statistics, 2017, data processing IOBE, Southern countries (Italy, Spain, Portugal). Percentage changes between 2009 and 2016 have been calculated in Fixed -rate Price Data (\$ 2010 PPS, OECD), ELSTAT 2017. For 2016 absolute numbers are estimation. Definitions of total and public health expenditure see annex 7.

Total health expenditure per capita (2016)

“ The significant reduction of public funding during 2010-2016, led to an increase of private health expenditure, thus each household contributing almost half of the total health expenditure in 2016. ”

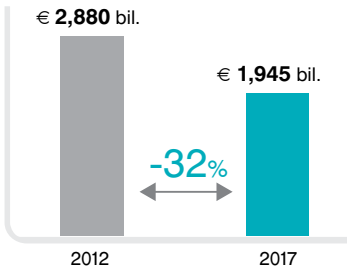


SOURCE: OECD Health Statistics 2017, Eurostat 2017, data processing IOBE, Southern countries (Italy, Spain, Portugal), EU23 data unavailable for the rest of the countries

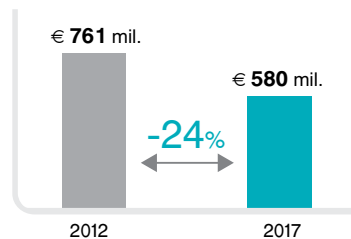
PHARMACEUTICAL EXPENDITURE

“ Significant decline of public pharmaceutical expenditure was recorded during 2012-2017 by -32% for retail products (outpatient), while similar decline is expected in public pharmaceutical expenditure for hospital products (inpatient) for 2018 at €530 mil. ”

Public outpatient pharmaceutical expenditure



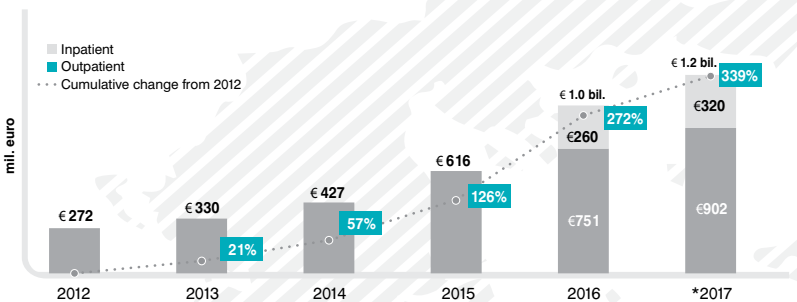
Public inpatient pharmaceutical expenditure



SOURCE: EOPYY notes 2012-2017, State budget 2014-2016, ESYNET 2012-2015, MD 681 (08/03/2012), MD 3035 (15/11/2012), MD 2045 (22/08/2013), MD 2243 (18/08/2014), MD 1803 (20/08/2015), Law No 4354 (A) MD 176 (26/12/2015), MD 2758 (18/12/2015), MD 241 (23 12 2016), MD 74 (19 05/2017), MD 2254 (30/06/2017), Law No 4486 (A) MD 115 (07/08/2017), MD 2758 (18/12/2015), Law No 4447 (A) MD 241 (23/12/2016), Law No (A) MD 201 (22/12/2017), data processing IOBE-SFEE.

Industry contribution on total pharmaceutical expenditure (clawback and rebate)

“ The significant decline of public pharmaceutical expenditure during 2012-2017, burdened the industry through flat mandatory returns and discounts (clawback and rebate) estimated at €1.2 bil. (industry contribution on total pharmaceutical expenditure) in 2017, recording unprecedented cumulative increase by +339% since 2012. ”

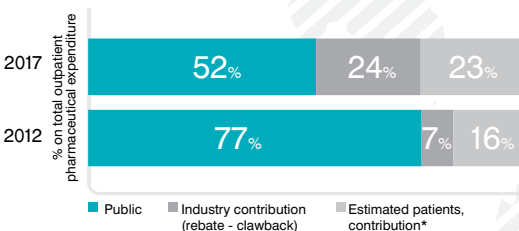


However, the industry remains a **pillar for investment** in Greece through expenditure on Research and Development (R&D) for new therapies and **with 2,265 clinical studies** irrespective of phase and stage (up to 2017), and with **64% of total employees** in the production of pharmaceuticals with **university education**.

SOURCE: EOPYY Notes 2012-2016, Notes 2016 ESY HOSPITALS, PAPAGEORGIOU Hospital, EOPYY *Estimations for 2017 and according to unofficial data from EOPYY and ESY Hospitals, data processing IOBE-SFEE. Note: 1A drugs (EOPYY) are not included in the outpatient pharmaceutical expenditure.

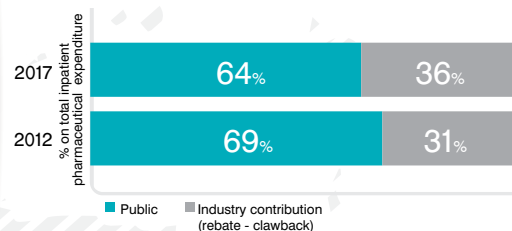
OUTPATIENT Financing by agency

“ Industry offers 1 out of 4 medicines in retail. ”



INPATIENT Financing by agency

“ Industry offers 1 out of 3 medicines in hospital. ”

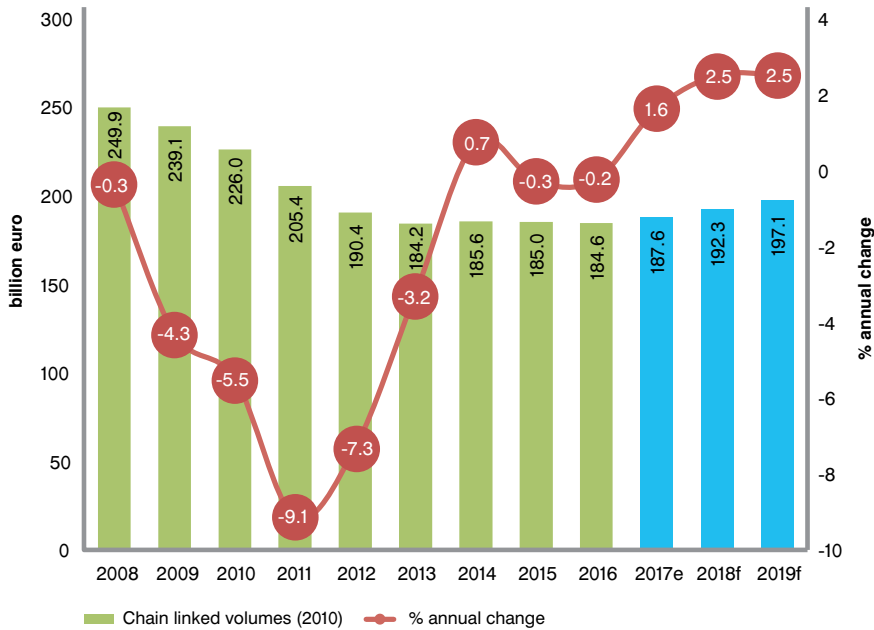


NOTE: *On the outpatient pharmaceutical expenditure, patients contribution should be included and estimated ~ 16-17% in 2012 and according to unofficial data EOPYY-HDIKA reached ~ 25% in 2017, while on a hospital level patients' contribution is zero.

2.1 MACROECONOMIC INDICATORS

Gross Domestic Product (GDP) of the Greek economy amounted to €184.6 bil. in 2016, decreased by -0.2% compared to 2015, remaining on a slightly reluctant path, with a recovery expected from 2017 onwards. For 2017, growth rate is projected at 1.6%, with a further strengthening of 2.5% over 2018-2019¹. For the period 2017-2018, the estimation of IOBE² is growth at lower levels, 1.3% and 2.0% respectively, with significant push from private and public consumption and investment, while for the same period the external sector (exports - imports) expected to remain neutral in the shaping of GDP.

Figure1: GDP (€) and annual change (%) - Greece

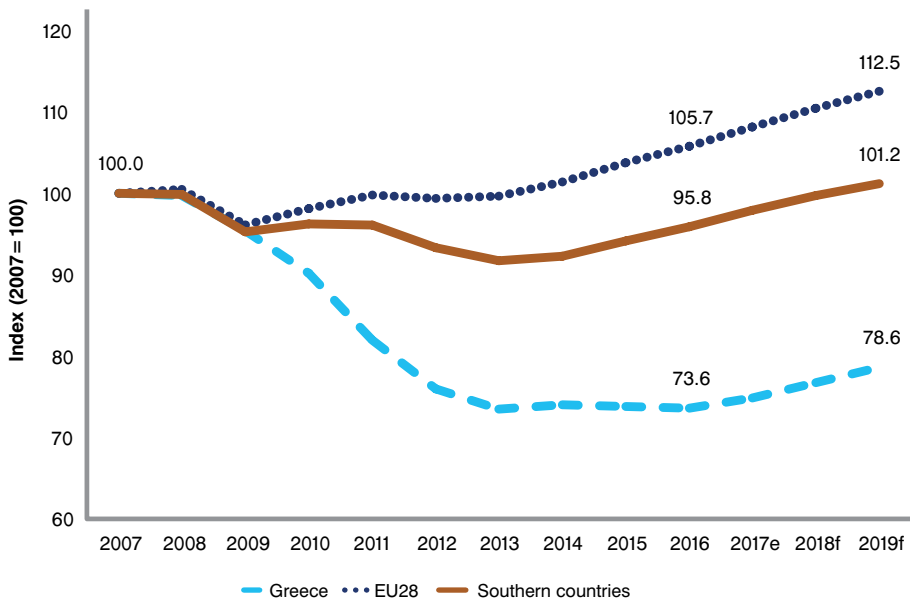


SOURCE: Eurostat, 2017, AMECO 2017 (Autumn 2017 Economic Forecast), GDP Chain linked volumes 2010

1. European Commission
 2. Greek Economy, 3rd quarter 2017

The result of the deep and continuous recession of the Greek economy had a significant impact on GDP, with the **cumulative GDP change** in 2016 standing at 73.6% of 2007 levels, that is a cumulative loss of -26.4%. On the contrary, Southern countries had smaller losses with total GDP in 2016 at 95.8% of 2007 levels, while in EU28 stronger GDP growth was recorded in 2016 at 105.7% of 2007 levels.

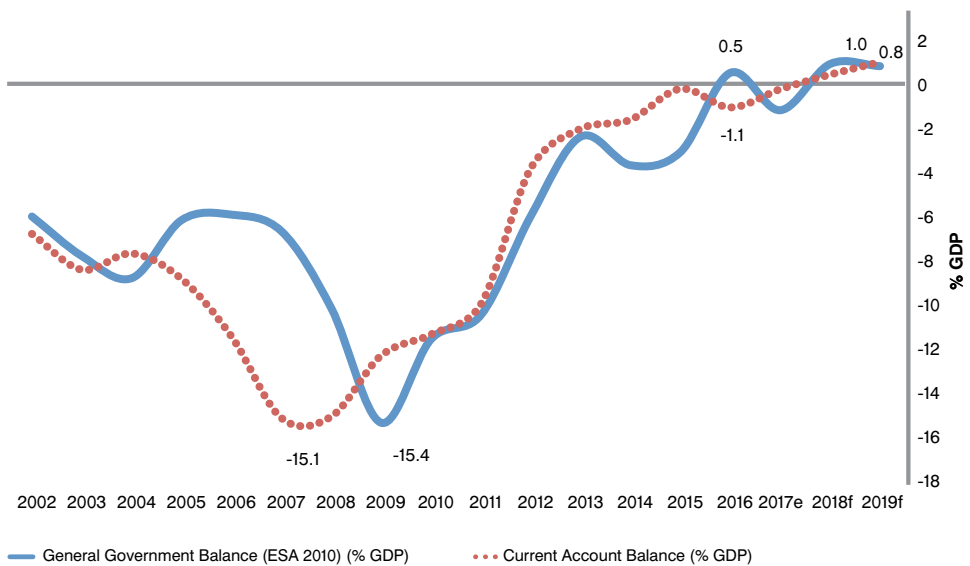
Figure 2: Index of cumulative GDP change (%) Greece-EU28-Southern countries



SOURCE: Eurostat, 2017, AMECO 2017 (Autumn 2017 Economic Forecast), GDP Chain linked volumes 2010, data processing IOBE, *Southern countries (Italy, Spain, Portugal)

The Greek economy has experienced a persistent recession, as a major economic adjustment program was implemented after 2010, with reduced public spending and increased taxation, resulting in a significant decline of GDP. The program corrected the imbalances of the Greek economy, both in the domestic sector (**General Government Balance**) and in the external sector (**Current Account Balance**). In particular, the very high deficits of -15.1% in 2008 in the current account balance and -15.4% in 2009 in the general government balance decreased significantly, with the latter indicating a positive sign in 2016 (+0.5 points) for the first time since 1979, while a significant correction was made to the current account balance with a sharp downturn in imports.

Figure 3: General Government Balance & Current Account Balance (% GDP)

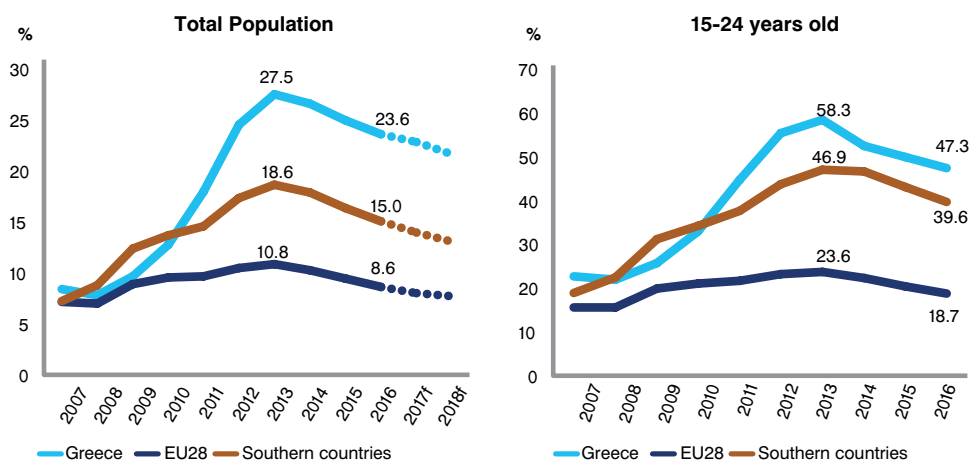


SOURCE: AMECO, 2017, GDP Chain linked volumes 2010, data processing IOBE. The government budget deficit also includes interest on debt repayment but does not include extraordinary entries in revenues and expenses due to the recapitalization of banks in 2012-2015. The external sector balance is reported in the current account balance and includes the balances of Goods and Services, Primary Income (Labour, Entrepreneurship) and Secondary Income (Current Transfers). General Government Balance does not include the impact of the support to the financial institutions from all interventions during the financial crisis on the General Government deficit.

2.2 SOCIAL ENVIRONMENT

The impact of the deep recession of the Greek economy resulted in high unemployment rate of the general population, with a stronger problem for young people aged 15-24. In Greece, the **unemployment rate of the general population** climbed to a historically high level of 27.5% in 2013, with a gradual improvement to 23.6% in 2016, still very high for a European country. With lower tension in Southern countries, unemployment rate reached 18.6% in 2013 and fell to 15.0% in 2016, lower than the unemployment rate in EU28.

Figure 4: Unemployment rate (% of total population) Greece-EU28-Southern countries

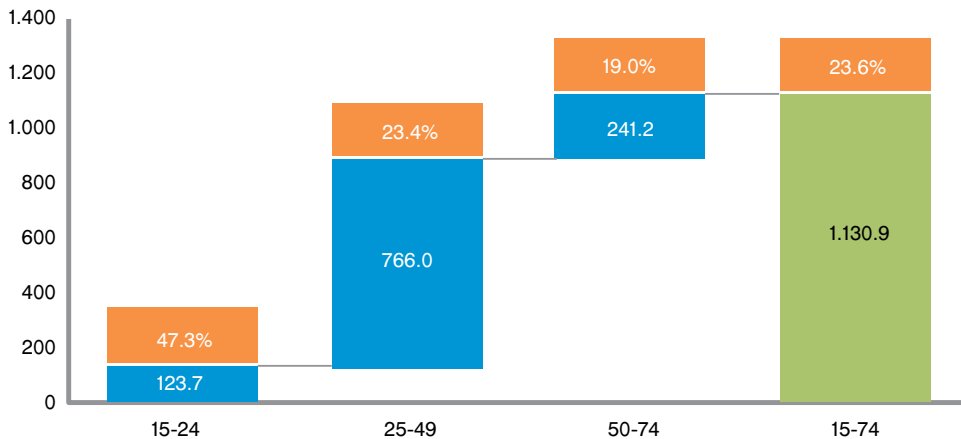


SOURCE: Eurostat 2017, European Commission Spring 2017 Economic Forecast, GDP Chain linked volumes 2010, data processing IOBE.
*Southern countries (Italy, Spain, Portugal)

The **unemployment rate among young people** aged 15-24 is much higher, and reached a peak of 58.3% in 2013, with almost 6 out of 10 young people out of the labour market, resulting in the brain drain of young and highly educated scientists abroad. A similar problem is found in the Southern countries, with youth unemployment rate over 40% in 2013, while much lower is the respective rate in EU28.

At the same time, in 2016 a high rate of **long-term unemployment** is recorded at 72% of the total unemployed, that is 813 thousand people remain out of the labour market for more than 12 months. The highest unemployment rate is found among young people aged 15-24, while in absolute numbers the largest number of unemployed comes from ages 25-49, the most productive age group, with about 766 thousand people unemployed.

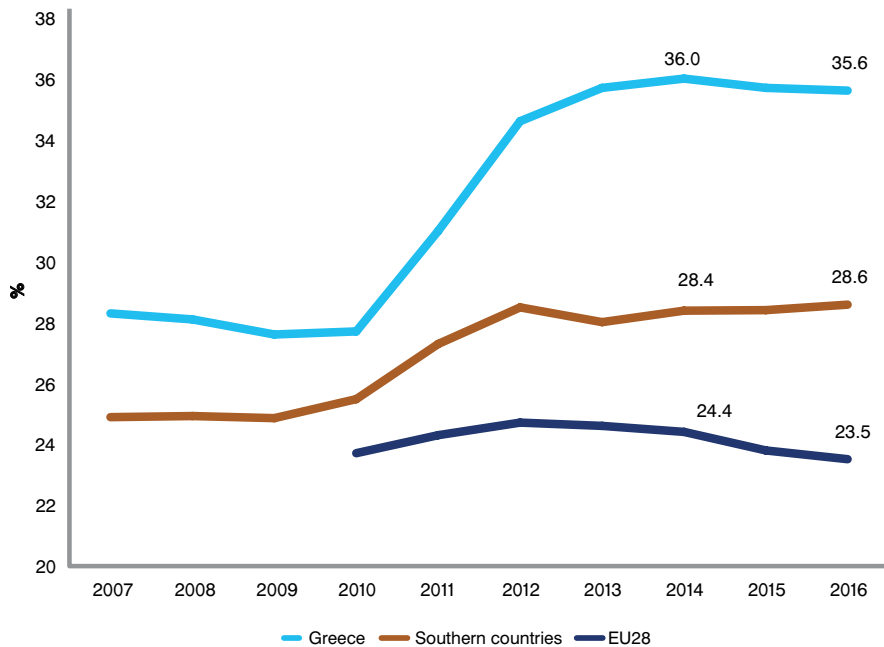
Figure 5: Number of unemployed (thousand people) and unemployment (% of total population) by age group - Greece (2016)



SOURCE: Eurostat, 2017 (percentages refer to the active population of this age group who are unemployed), data processing IOBE

The decrease in the national income and the significant increase of unemployment led a large part of the population at risk of poverty, ie people with income below 60% of median income. In Greece, the **proportion of the population at risk of poverty** reached 36% of the total population in 2014, a high figure taking into account that the income threshold has declined significantly in 2014 and slightly narrowed in 2016. In Southern countries that implemented similar fiscal adjustment program population at risk of poverty was close to 29%, well below the level of Greece.

Figure 6: Poverty risk (% of total population) Greece-EU28-Southern countries



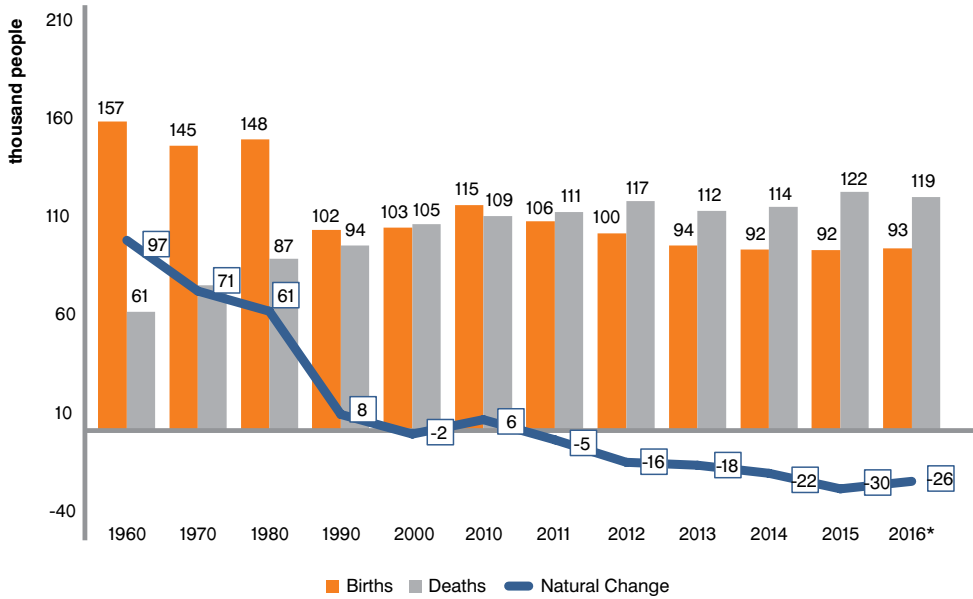
SOURCE: Eurostat, 2017, data processing IOBE. Percentage of people at poverty risk: percentage of people with disposable income below 60% of the national median income. Median income is the income above which is the 50% of the population. * Southern countries (Italy, Spain, Portugal)

DEMOGRAPHIC TRENDS AND HEALTH PROFILE OF THE POPULATION

3.1 NATURAL POPULATION CHANGE

The number of births in Greece amounted to 93 thousand people in 2016 recording a 1.0% increase from previous year, while the number of deaths recorded a decrease of -2.3%, amounting to 119 thousand people compared to 122 thousand people the previous year. As such, **the natural population change (difference births - deaths)** was negatively affected in 2016, resulting in an overall reduction of -26 thousand people in the national population, -186 thousand people in Southern countries and -117 thousand people in EU28.

Figure 7: Natural change of population (thousand people)-Greece

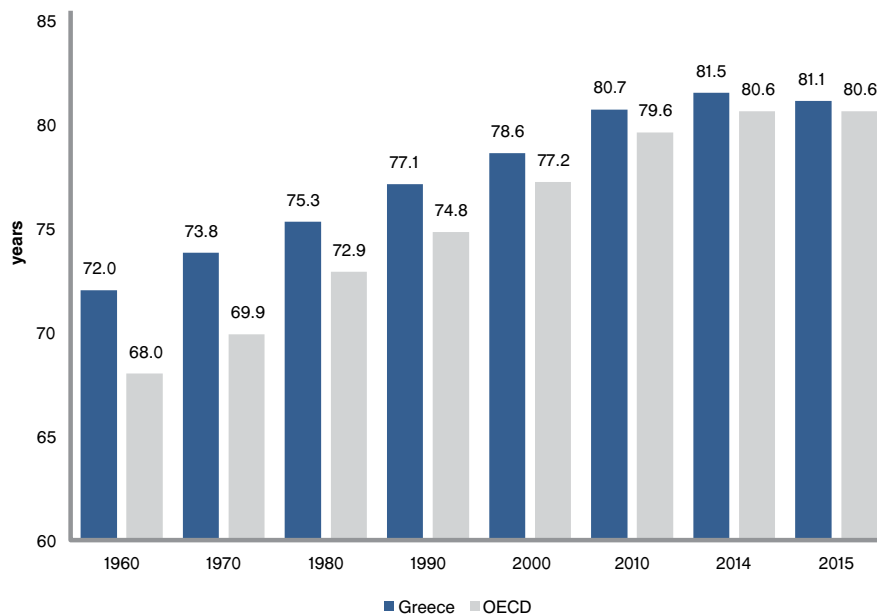


SOURCE: EL. STAT., 2017* Provisional data **Natural change is defined as the change due only to the difference in births - deaths without taking into account immigration *** The number of births does not include stillbirths, which in 2016 amounted to 339

3.2 LIFE EXPECTANCY

Life expectancy in Greece has increased considerably by 9.1 years during 1960-2015, partially explained by the technological advances, improvement in the provision of healthcare services, contribution of R&D and introduction of innovative new drugs and therapies.

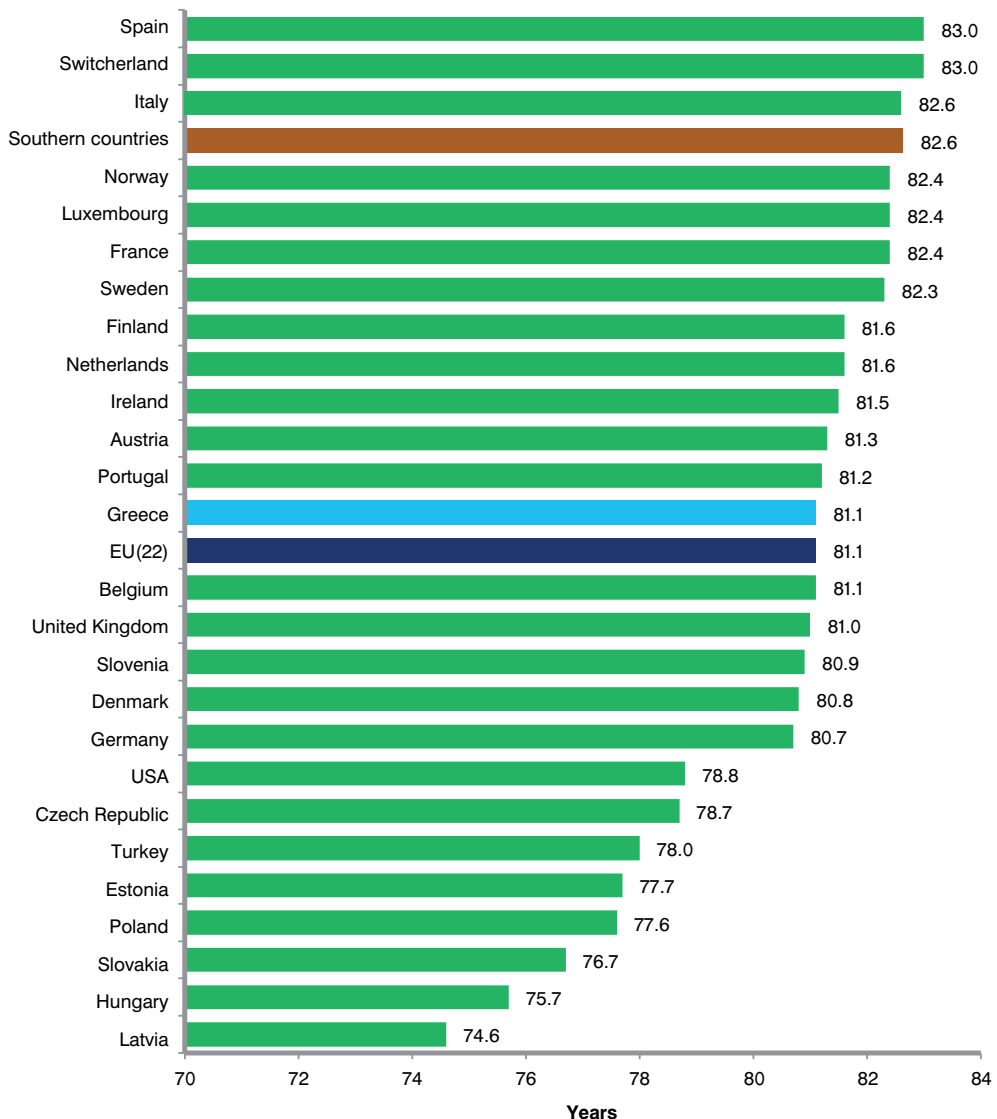
Figure 8: Evolution of life expectancy at birth (years) Greece-OECD



SOURCE: OECD, Health Statistics 2017

Life expectancy in Greece reached 81.1 years in 2015, which is similar to EU22 average and lower than in Southern countries (82.6). According to UN projections, life expectancy in Greece is expected to reach 84 years in 2030. The highest life expectancy was recorded in Spain, Switzerland and Italy.

Figure 9: Life expectancy at birth (years) Greece-EU22-Southern countries (2015)

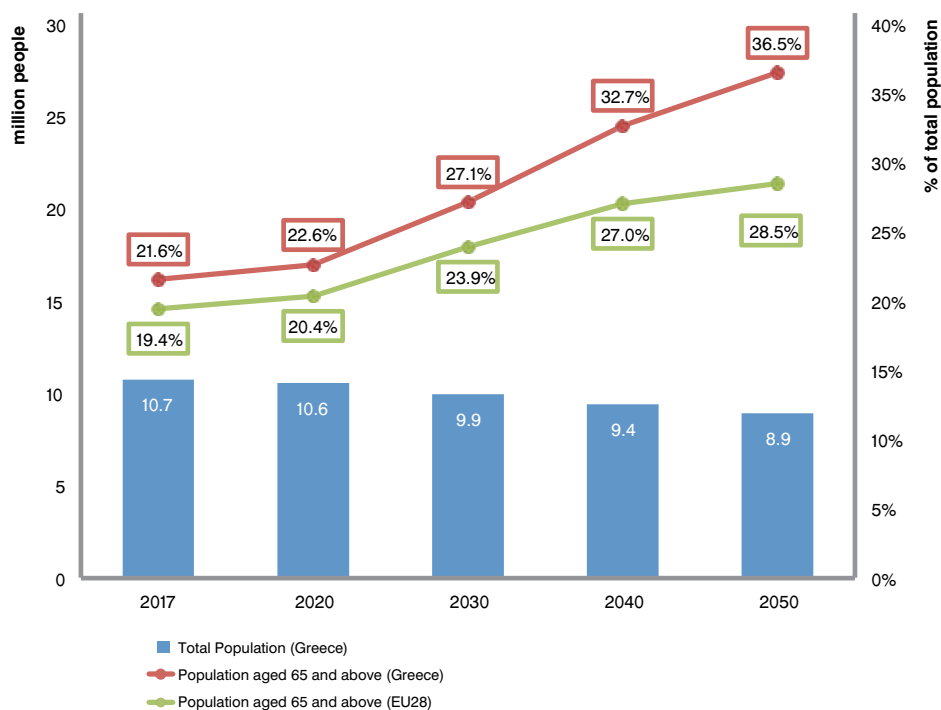


SOURCE: OECD, Statistics 2017, data processing IOBE *Southern countries (Italy, Spain, Portugal)

3.3 AGING POPULATION

Based on the latest revision from Eurostat, the steady decline of the population is expected to continue until 2050. In 2017, **the percentage of people aged 65 and above in Greece** in Greece is expected to increase from 22.6% of the total population in 2020 (21.8% in Southern counties, 20.4% in EU28) to reach 36.5% in 2050.

Figure 10: Population aged 65 and above (% total population) Greece-EU28

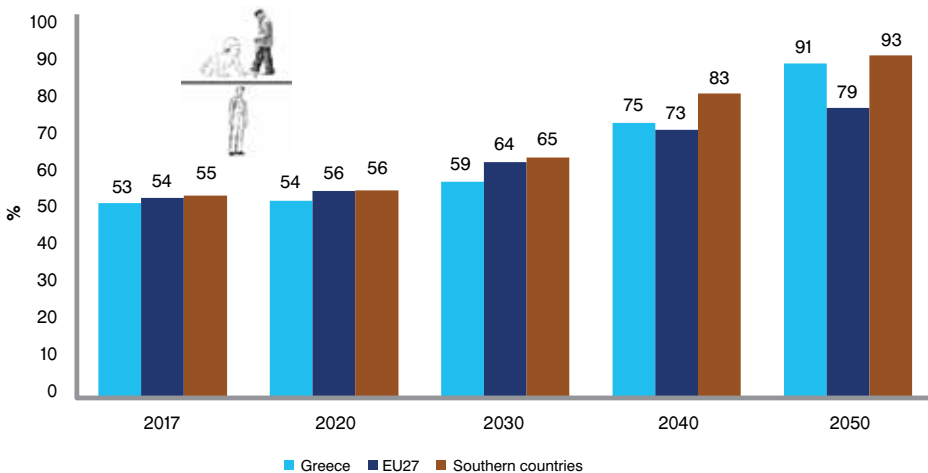


SOURCE: Eurostat, Population Projections, 2017, data processing IOBE *Not included the possible legalization of migration from 2015 onwards

3.4 DEPENDENCY RATIO

The demographic changes directly affect population's dependency ratio. In Greece, nearly half of the population is dependent on the other half, and this proportion is expected to grow, signaling deterioration and increased pressure on the social security system, following the general trend of the developed countries. In 2017, Greece's dependency ratio reaches 53%, meaning that **for every 2 active people there is 1 inactive**, close to EU28 average (54%) and lower than the average of Southern countries (55%). According to the United Nations, the dependency ratio in Greece is estimated to reach 91% by 2050, and 93% in Southern countries while in EU27, deterioration in the dependency ratio is also expected, but in a slower pace during the same period (79%).

Figure 11: Dependency ratio (%) Greece-EU27-Southern countries

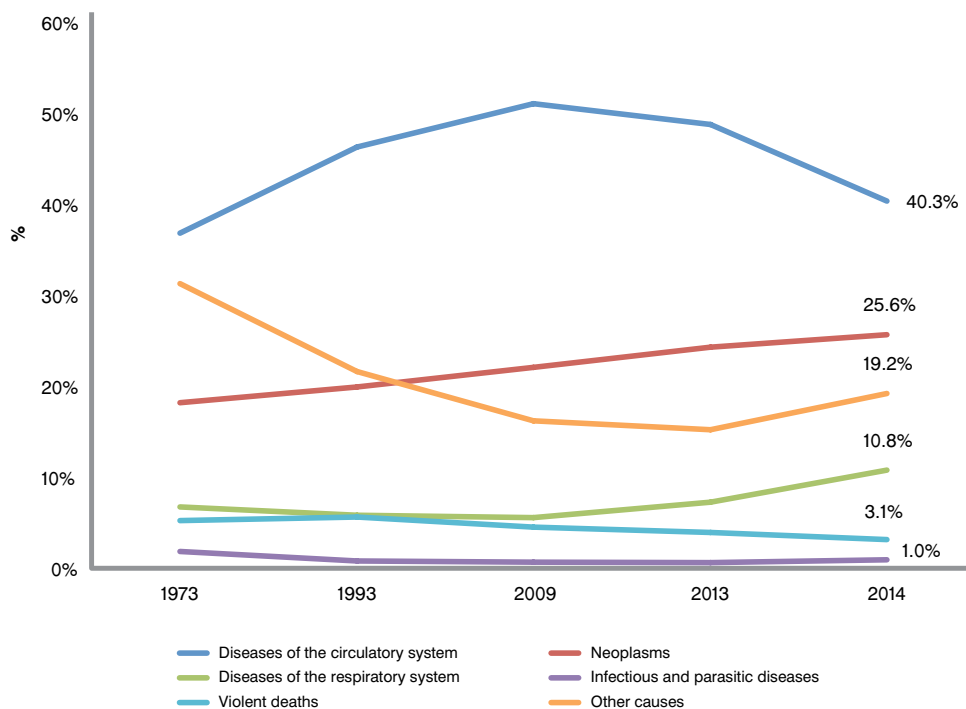


SOURCE: United Nations, World Population Prospects: The 2017 Revision, data processing IOBE *Southern countries (Italy, Spain, Portugal)
******Dependency population ratio shows the number of dependents (aged 0-14 and over the age of 65) to the total active population (aged 15-64). A high ratio means that the overall economy faces a greater burden in supporting the ageing population. This indicator is on an upward trend in advanced economies, reflecting rising life expectancy and declining birth rates. *******EU27 (non available data for Cyprus)

3.5 CHRONIC DISEASES- CAUSES OF DEATH

Over time, a **significant increase in the deaths due to circulatory system diseases** is recorded, responsible for 40.3% of total deaths, despite the decline in recent years, while increase in neoplasms is recorded, accounting for 25.6% of total deaths. Interestingly, the increase in the share of diseases of the respiratory system after 2009, after a stabilization period, and finally the violent deaths and infectious and parasitic diseases compose a small part of the total deaths.

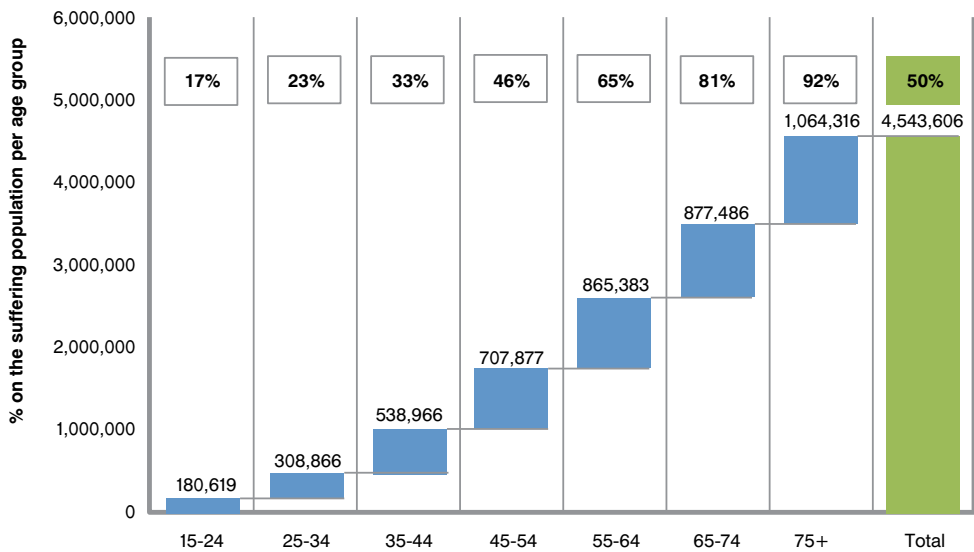
Figure 12: Causes of death (% of total deaths) - Greece



SOURCE: EL.STAT., 2016 data processing IOBE *Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations. Other causes: Diseases of the digestive system, Diseases of the genitourinary system, Diseases of the nervous system and sense organs, Endocrine and metabolic diseases, nutritional deficiencies and immune disorders

In Greece, about 4.5 million people have experienced a **chronic health problem or chronic disease** in 2014, with 62% of them aged above 55 years old. However, the majority of people above 75 years old (92%) experienced a chronic health problem or chronic disease. Taking into account the increase in life expectancy and the aging population, health systems are further pressed as this age group consumes most health resources.

Figure 13: Population suffering from chronic disease (mil. people) per age group (2014)



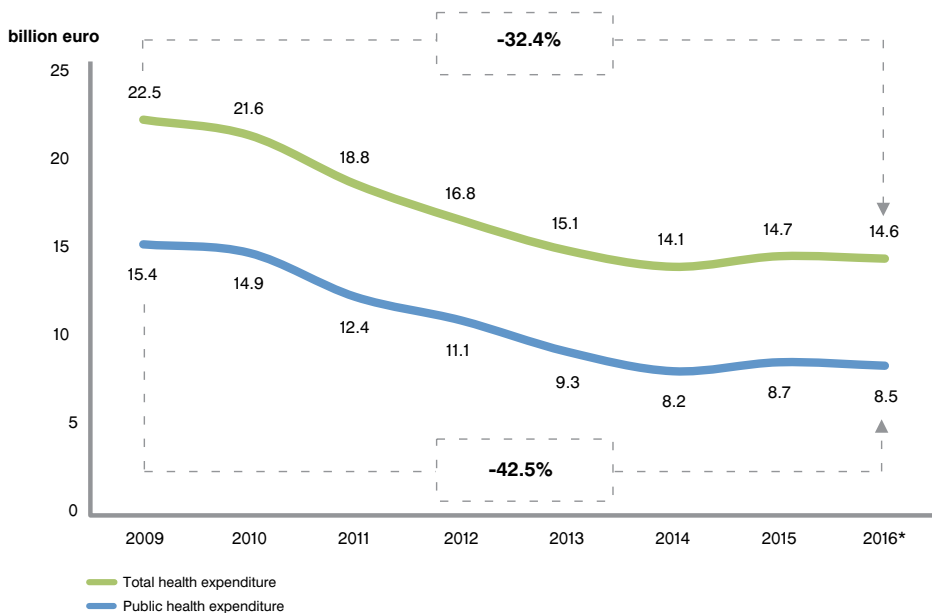
SOURCE: EL.STAT., 2016. Health Survey: 2014, data processing IOBE

DEMAND SIDE: HEALTH AND PHARMACEUTICAL EXPENDITURE

4.1 FUNDING OF HEALTH EXPENDITURE

In 2016, **total health expenditure** in Greece amounted to €14.6 bil., out of which €8.5 bil. composes public health expenditure. Total health expenditure declined by -32.4% during 2009-2016, while **public health expenditure** decreased by -42.5%.

Figure 14: Total and public health expenditure (bil. €)

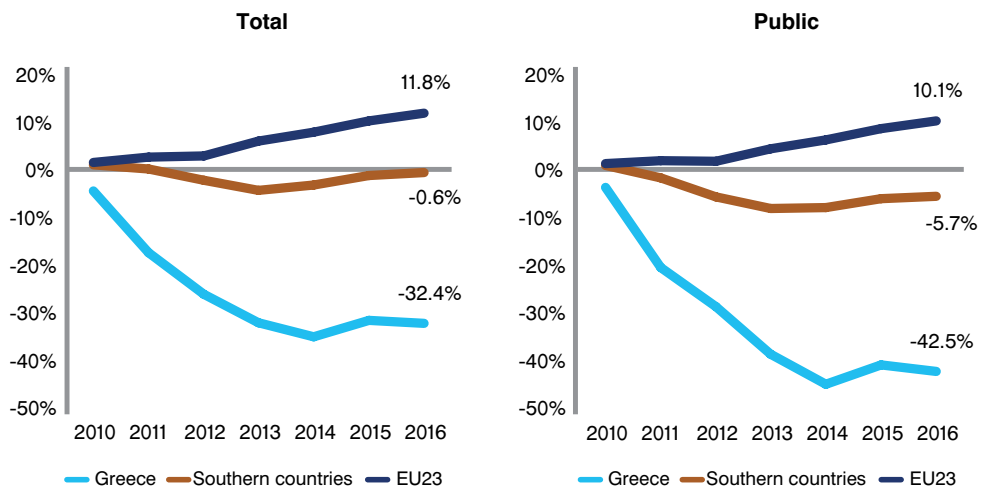


SOURCE: System of Health Accounts (SHA) 2015, EL.STAT., 2017, OECD Health Statistics, 2017. data processing IOBE

* For 2016 is estimated percentage **Percentage changes between 2009 and 2016 have been calculated in the Fixed-rate Price Data (\$ 2010 PPS, OECD). For the definitions of total and public funding on health expenditure, see Annex.

The **index of GDP cumulative change in total health expenditure** showed a decline of -0.6% in Southern countries, while an increase of +11.8% was recorded in EU23 (a decrease of -32.4% in Greece during the same period) Similarly, a cumulative decline of -5.7% was recorded in public health expenditure in Southern countries, while an increase of +10.1% was noted for EU23 (-42.5% decrease in Greece during the same period).

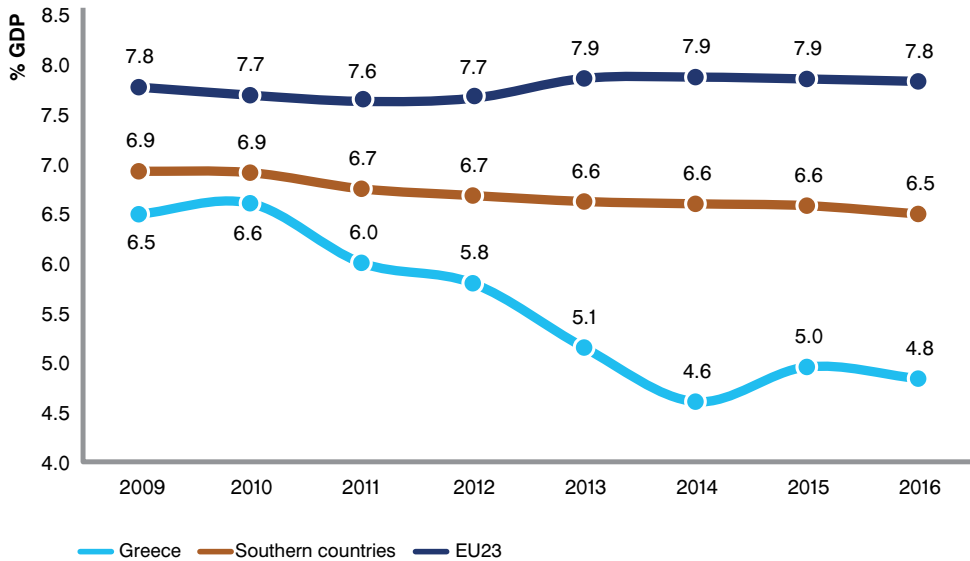
Figure 15: Index of cumulative change on health expenditure (%) Greece-EU23-Southern countries



SOURCE: System of Health Accounts (SHA) 2015, OECD Health Statistics, 2017, IOBE data processing *Southern countries (Italy, Spain, Portugal) ** Percentage changes between 2009 and 2016 have been calculated in the Fixed-rate Price Data (\$ 2010 PPS, OECD).

In Greece, total health expenditure as a percentage of GDP accounted to 9.5% (2009) and decreased at 8.2% (2016), indicative of a faster reduction in health expenditure compared to GDP reduction during the same period. **Public health expenditure as a percentage of GDP** in Greece amounted to 4.8% in 2016 compared to 6.5% in 2009. This evolution shaped the rate of public health expenditure in Greece below EU23 average (7.8%), which remains almost stable during 2009-2016. In Southern countries that implemented economic adjustment programs, the percentage was at 6.5% for 2016.

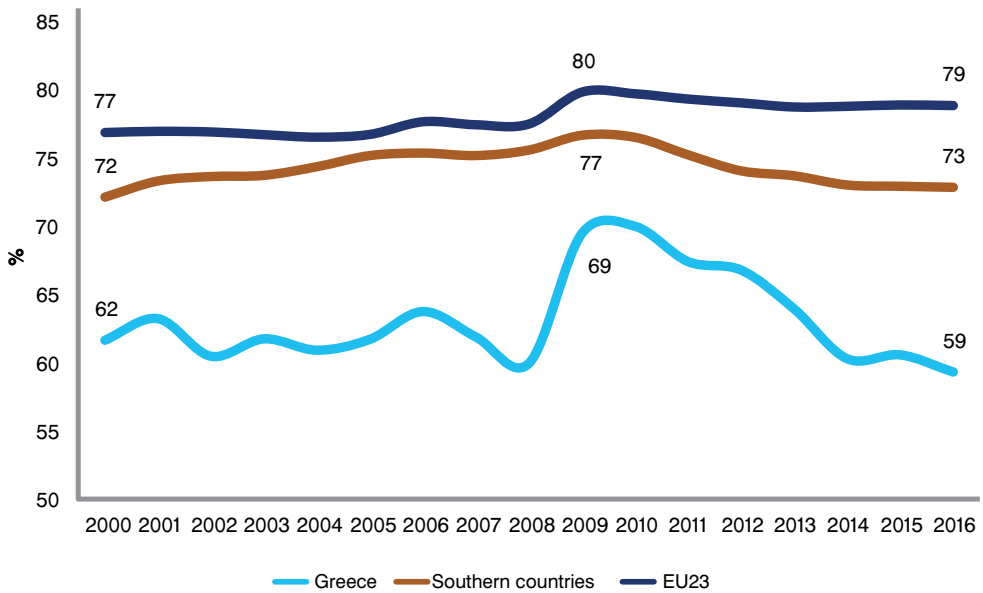
Figure 16: Public health expenditure (% GDP) Greece-EU23-Southern countries



SOURCE: System of Health Accounts (SHA) 2015, EL. STAT., 2017, OECD Health Statistics, 2017, data processing IOBE
*Southern countries (Italy, Spain, Portugal) **EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Special attention should be given to the **evolution of health expenditure by funding agency**, summing the public (General Government and Social Security Funds) and private (Private Insurance & Private Payments), during 2000-2016. The decline in public health expenditure led to an increase in the private contribution on health expenditure estimated at 41% in 2016, while in Southern countries and EU23 private health expenditure was 27% and 21%, respectively.

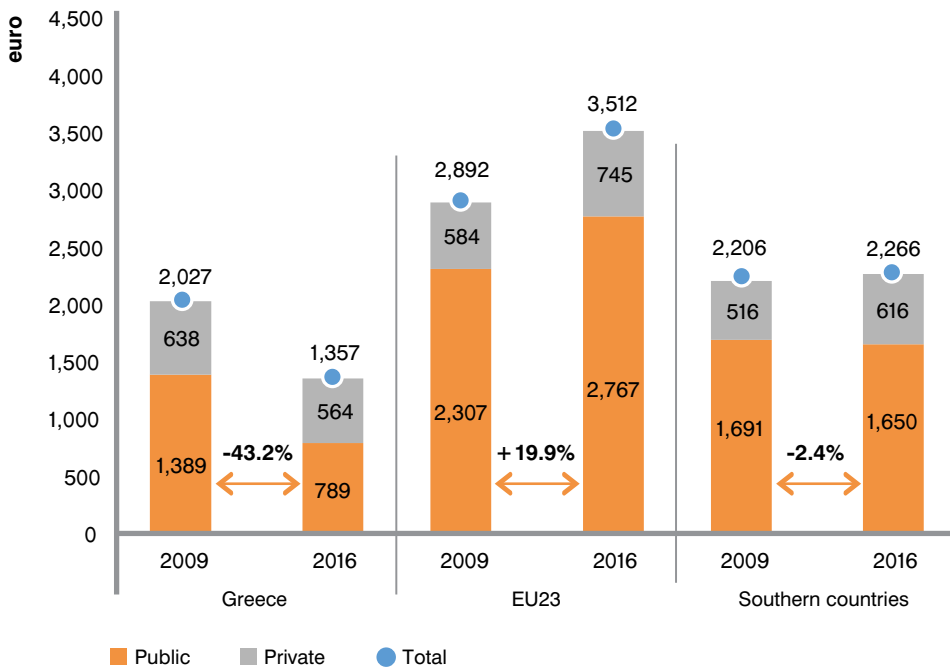
**Figure 17: Public health expenditure (% of total expenditure)
Greece-EU23-Southern countries**



SOURCE: OECD Health Statistics, 2017, data processing IOBE. * Southern countries (Italy, Spain, Portugal)

Total health expenditure per capita in Greece amounted to €1,357 in 2016 compared to €2,027 in 2009, that is €909 less than the average of Southern countries. **Public health expenditure per capita** declined in Greece by -43.2% between 2009 and 2016, and amounted to €789 compared to an increase of +19.9% in EU23 and a slower decline in Southern countries of -2.4% during the same period.

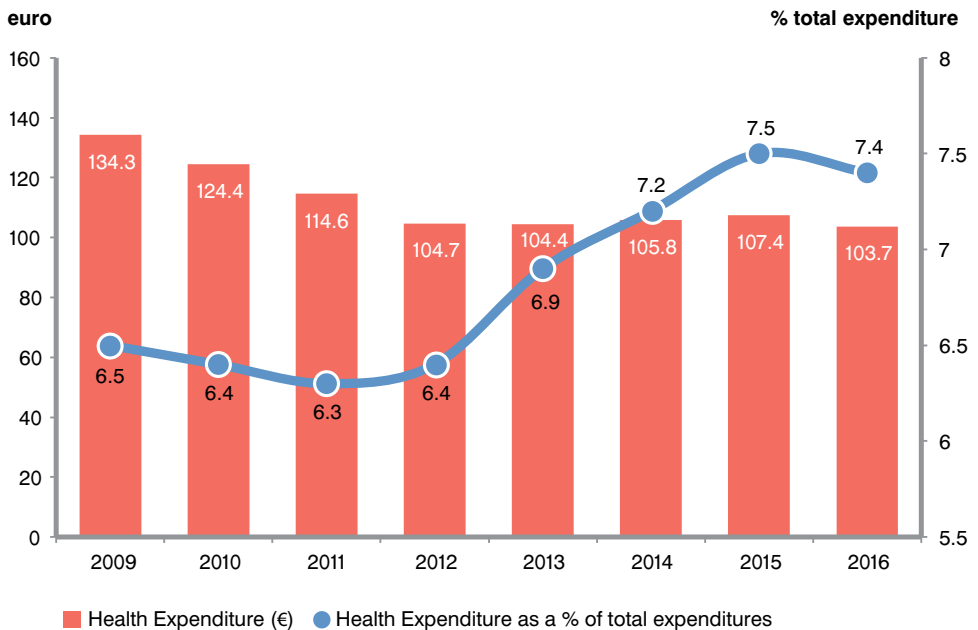
Figure 18: Total per capita health expenditure Greece-EU23-Southern countries



SOURCE: OECD Health Statistics, 2017, data processing IOBE * Southerncountries (Italy, Spain, Portugal) ** EU 23 due to unavailability of data for other countries

Households' monthly health expenditure was contracted by -23% during 2009-2016, when it reached €103.7, which accounted for 7.4% of total household expenditure (6.5% in 2009), indicating households' reduced purchasing power and increased participation in health expenditure.

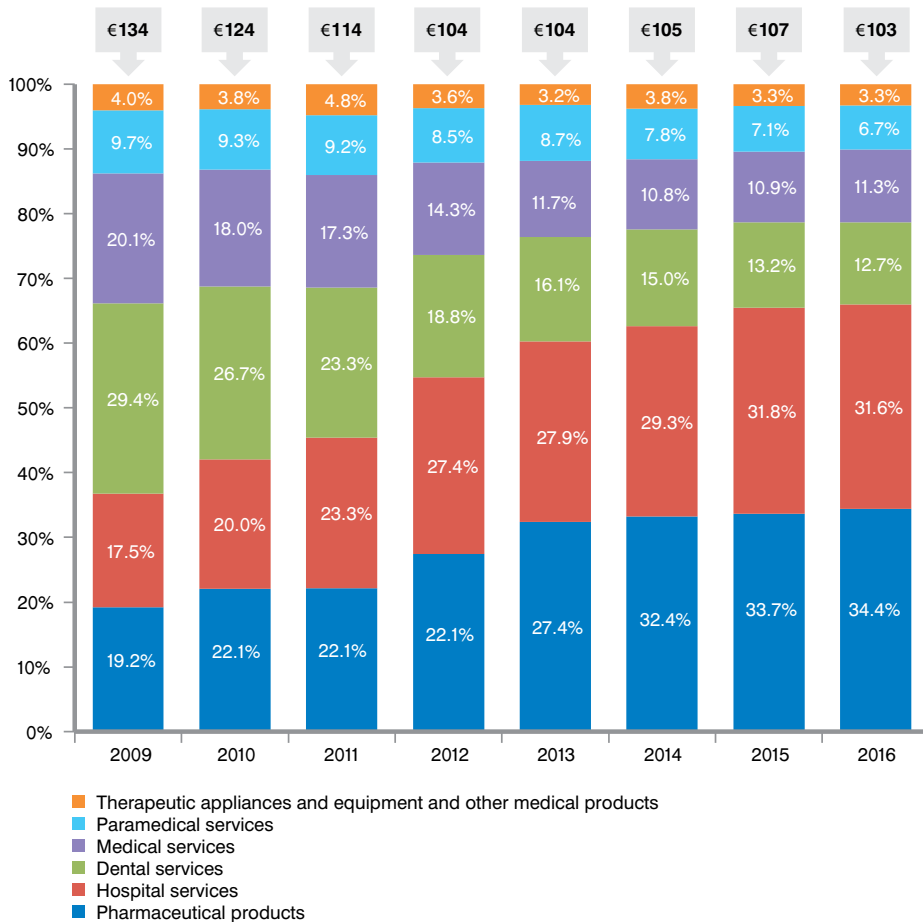
Figure 19: Health expenditure of households (€) per month-Greece



SOURCE: EL.STAT., 2017, data processing IOBE * Household Budget Survey, which is conducted annually by the ELSTAT, provides information for the composition of total household spending, according to various socioeconomic characteristics of each household..

During the economic crisis period, there was a shift of household expenditure mainly towards pharmaceutical and hospital care. Specifically, from €103 monthly health expenditure per household, 34.4% refers to pharmaceuticals and 31.6% to hospital services, 12.7% to dental services and 11.3% to other medical services.

Figure 20: Breakdown of household health expenditure (%) per month - Greece

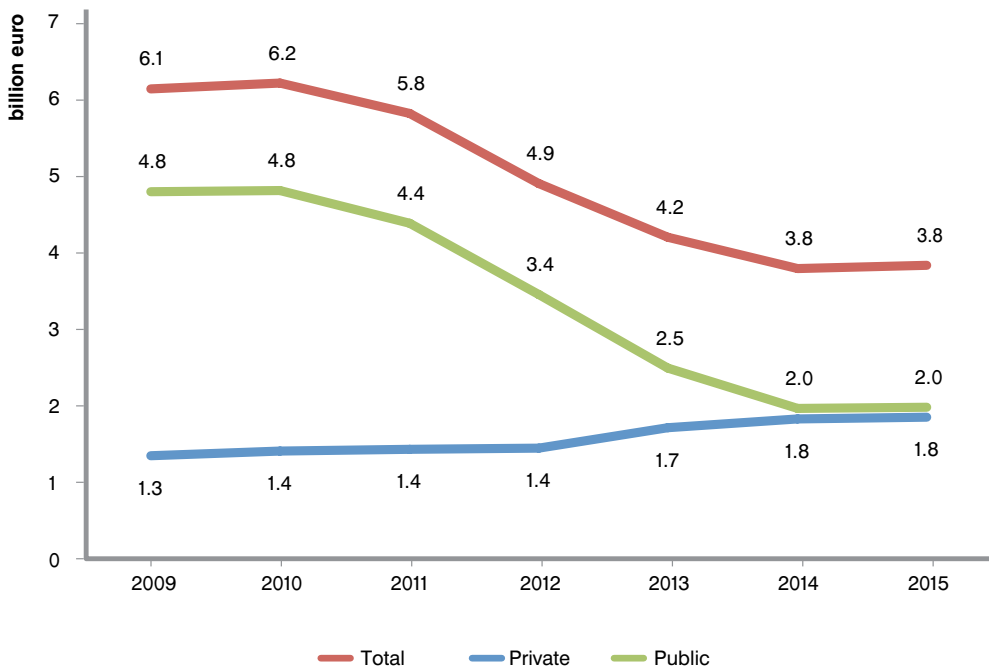


SOURCE: EL.STAT., 2017. data processing IOBE

4.2 PHARMACEUTICAL EXPENDITURE

Total expenditure for pharmaceuticals and other medical non durable goods accounted for €3.8 billion in 2015, recording a decrease of -37.6% compared to 2009. Correspondingly, **public expenditure for pharmaceuticals and other medical non durable goods** from €4.8 billion in 2009 amounted to 2 bil. in 2015, recording a further decline of -58.7%, while **private expenditure for pharmaceuticals and other medical non durable goods** increased from €1.3 billion in 2009 to €1.8 billion 2015.

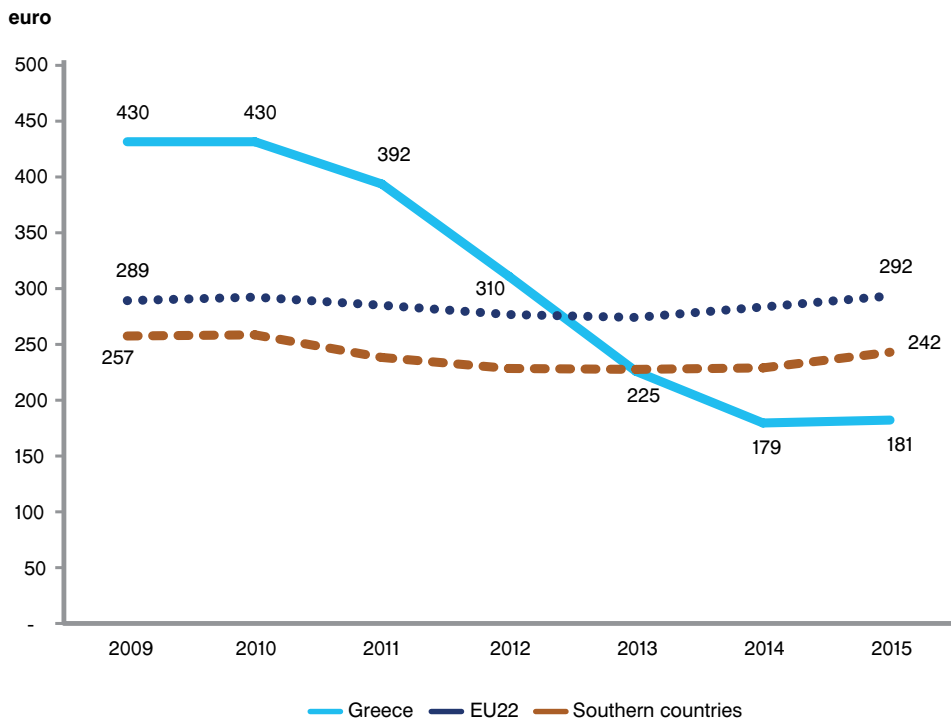
Figure 21: Total expenditure for pharmaceuticals and other medical non durable goods (bil. €)-Greece



SOURCE: System of Health Accounts (SHA) 2015, EL.STAT., 2017, data processing IOBE. * Expenditure for pharmaceuticals and other medical goods, as reported in the OECD and SHA, includes expenditure on final consumption by outpatients of prescription and non-prescription pharmaceuticals, on-patented and generics. Medical goods are also recorded in the same category (see Annex). According to the OECD and SHA, pharmaceutical expenditure is a broader category (HC.5.1), including prescription pharmaceutical products (HC.5.1.1), OTC (HC.5.1.2) and other medical goods (HC.5.1.3). Therefore, the total expenditure for pharmaceuticals and other medical goods includes, besides spending on prescription pharmaceuticals, a set of subcategories that have not yet been valued.

Similarly, a downward trend was observed in **public per capita expenditure for pharmaceuticals and other medical non durable goods**, from €430 in 2009 to €181 in 2015. Public per capita expenditure for pharmaceuticals and other medical non durable goods in EU22 increased from €289 in 2009 to €292 in 2015 approximately €100 higher than Greece, while in Southern countries was €242.

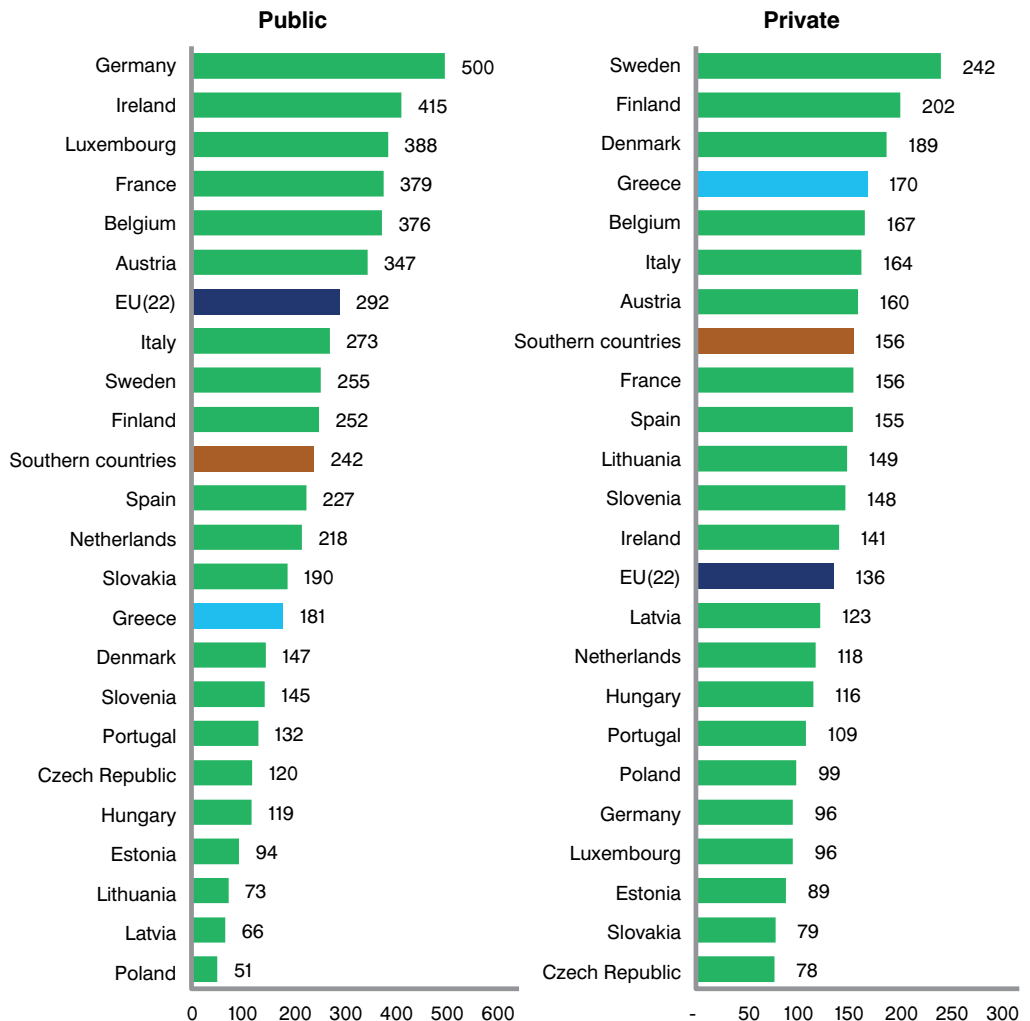
Figure 22: Public per capita expenditure for pharmaceuticals and other medical non durable goods Greece-EU22-Southern countries



SOURCE: OECD Health Statistics 2017, Eurostat 2017, data processing IOBE. * Southern countries (Italy, Spain, Portugal), ** EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK)

More specifically, the higher public per capita expenditure for pharmaceuticals and other medical non durable goods was recorded in Germany, Ireland and Luxembourg, while Greece (€181) is below the average of EU22 (€292). On the contrary, **private per capita expenditure for pharmaceuticals and other medical non durable goods** in Greece (€170) is higher than the average of EU22 (€136), ranking 4th among EU countries.

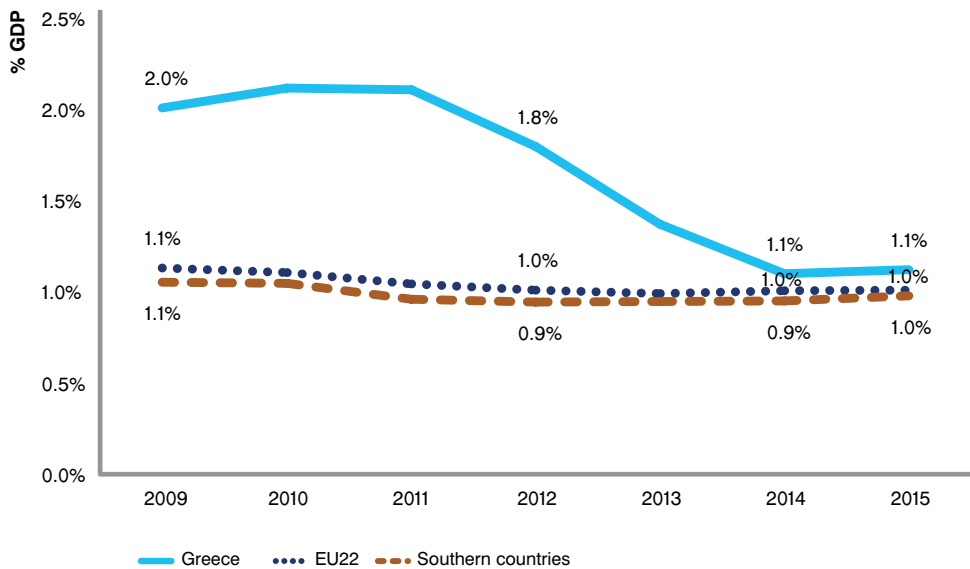
Figure 23: Public & private per capita expenditure for pharmaceuticals and other medical non durable goods (2015)



SOURCE: OECD Health Statistics 2017, Eurostat 2017, IOBE data processing, * Southern countries (Italy, Spain, Portugal), ** EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK)

Public expenditure for pharmaceuticals and other medical non durable goods as a percentage of GDP in Greece is estimated at 1.1% of GDP in 2015 compared to 2% in 2009, close to EU22 and Southern countries.

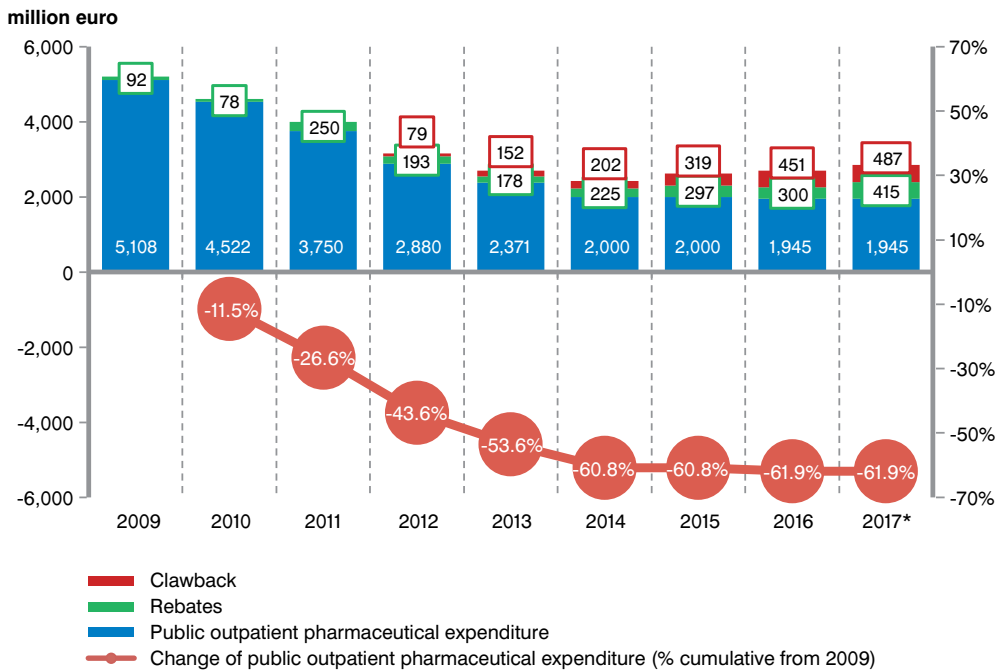
Figure 24: Public expenditure for pharmaceuticals and other medical non durable goods (% GDP) Greece-EU22-Southern countries



SOURCE: OECD Health Statistics 2017, Eurostat 2017, IOBE data processing, * Southern countries (Italy, Spain, Portugal), ** EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta, UK)

Public outpatient pharmaceutical expenditure amounted to €1,945 bil. in 2017 (and 2018) compared to €5.1 bil. in 2009, resulting in an overall decrease by -61.9% during 2009-2017. Accordingly, there was a significant increase in the contribution of pharmaceutical industry through mandatory returns and discounts (clawback and rebates). Specifically, in 2017 industry's contribution was €902 mil. recording an increase of 20% in comparison to previous year.

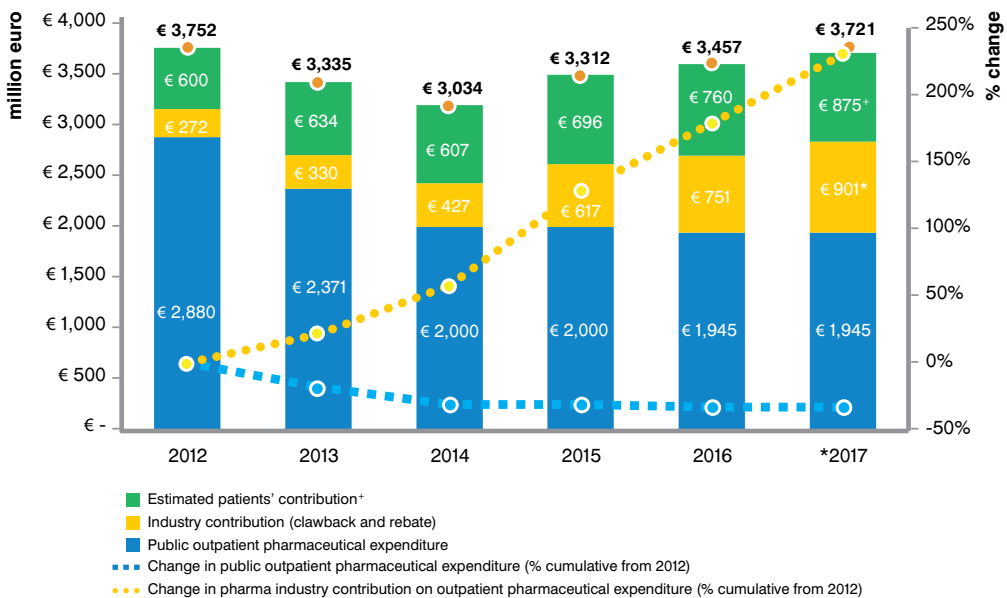
Figure 25: Outpatient pharmaceutical expenditure (excluding patients' contribution)



SOURCE: EOPYY 2012-2017, State Budget 2014-2016, Government Gazette 681 (08/03/2012), Gov. Gazette 3035 (15/11/2012), Gov. Gazette 2045 (22/08/2013), Gov. Gazette 2243 (18/08/2014), Gov. Gazette 1803 (20/08/2015), Law 4354 (A) Gov. Gazette 176 (26/12/2015), Gov. Gazette 2758 (18/12/2015), Gov. Gazette 241 (23.12.2016), Gov. Gazette 74 (19.05 / 2017) , Law 4486 (A) Gov. Gazette 115 (07/08/2017), Data processing IOBE-SFEE. It is worth noting that out of the public outpatient pharmaceutical expenditure for the second half of 2017 will be deducted the amount of €28.97 million from the implementation of the closed budget for hepatitis (Government Gazette 3197 12/09 / 2017). 1A drugs for hospital use are not included in the outpatient pharmaceutical expenditure over the period 2013-2015.

Total outpatient pharmaceutical expenditure (including estimated patients' contribution) amounted to ~€3.7 bil. in 2017, remaining close to 2012 levels, highlighting the actual needs of Greek patients for pharmaceutical coverage. However, the significant decline in public outpatient pharmaceutical expenditure by -32% during 2012-2017 resulted in a shift towards private contribution, with 50% increase on estimated patients' contribution and 230% increase on industry's contribution over the same period. For 2017, estimated patients' and industry's contribution reached 50% of total outpatient pharmaceutical expenditure.

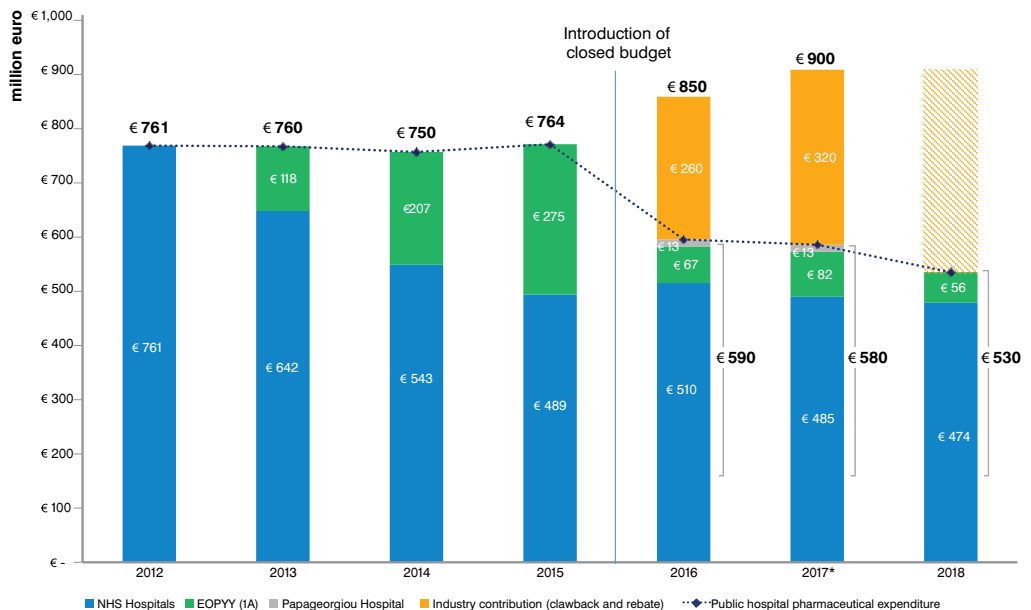
Figure 26: Total outpatient pharmaceutical expenditure



SOURCE: EOPYY 2012-2017, State Budget 2014-2016, Government Gazette 681 (08/03/2012), Gov. Gazette 3035 (15/11/2012), Gov. Gazette 2045 (22/08/2013), Gov. Gazette 2243 (18/08/2014), Gov. Gazette 1803 (20/08/2015), Law 4354 (A') Gov. Gazette 176 (26/12/2015), Gov. Gazette 2758 (18/12/2015), Gov. Gazette 241 (23.12.2016), Gov. Gazette 74 (19.05 / 2017), Law 4486 (A') Gov. Gazette 115 (07/08/2017), Data processing IOBE-SFEE. Patients' contribution during 2012-2017 is estimated at 16% - 25% based on unofficial data from EOPYY and IDIKA. 1A drugs for hospital use are not included in the outpatient pharmaceutical expenditure over the period 2013-2015.

Public hospital pharmaceutical expenditure was set at €530 mil. for 2018, decreased by -30% compared to 2015 (€764 mil.), before introducing closed budget (Official Gazette No 4354 A Government Gazette 176 16/12 2015). The reduction of public hospital pharmaceutical expenditure resulted in a shift towards industry (at hospital level patients' contribution is zero), through flat mandatory returns and discounts (clawback and rebate), estimated at €260 mil. for 2016 and €320 mil. for 2017 (35% of total hospital expenditure).

Figure 27: Hospital pharmaceutical expenditure



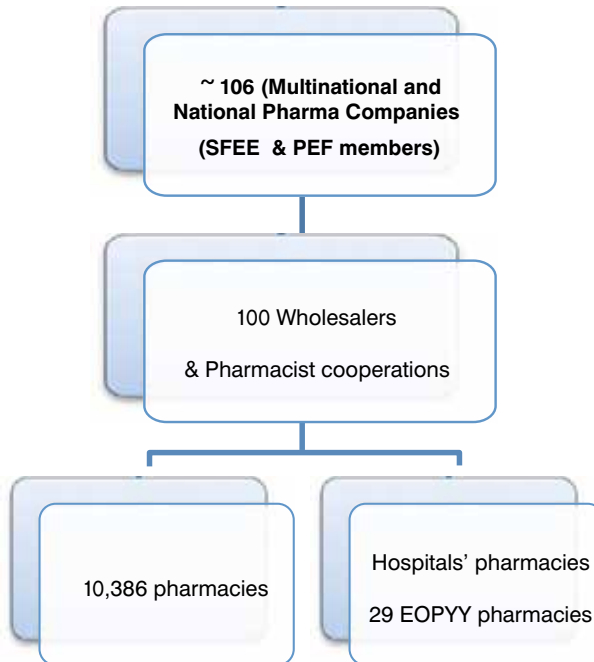
SOURCE: Law 4354 (A ') Government Gazette 176 (16/12/2015), GG 2758 (18/12/2015), GG 241 (23/12/2016), N.4509 A 'Government Gazette 201 (22/12/2017), data processing IOBE-SFEE. Note: 2018 estimation for industry participation as of 2017. Note: Public hospital pharmaceutical expenditure: EOPYY 2012-2017 ESYNET 2012-2015. Public hospital pharmaceutical expenditure covers ESY hospitals, EOPYY pharmacies, Papageorgiou. * Clawback: for 2016 based on notes from ESY hospitals, EOPYY and Papageorgiou, while for 2017 estimations and based on unofficial data from NHS hospitals and EOPYY, for Papageorgiou hospital estimation as of 2016. ** Rebate: for 2016 rebate was calculated on a scalable basis (5% of hospital price and an additional 1.5%) estimated at €5 million for NHS hospitals, for EOPYY based on 2016 notes, no available data for Papageorgiou hospital; for 2017 estimations and based on unofficial data.

CHAPTER 5

SUPPLY SIDE: PHARMACEUTICAL INDUSTRY AND ECONOMY

5.1 SUPPLY CHAIN FOR PHARMACEUTICAL PRODUCTS IN GREECE

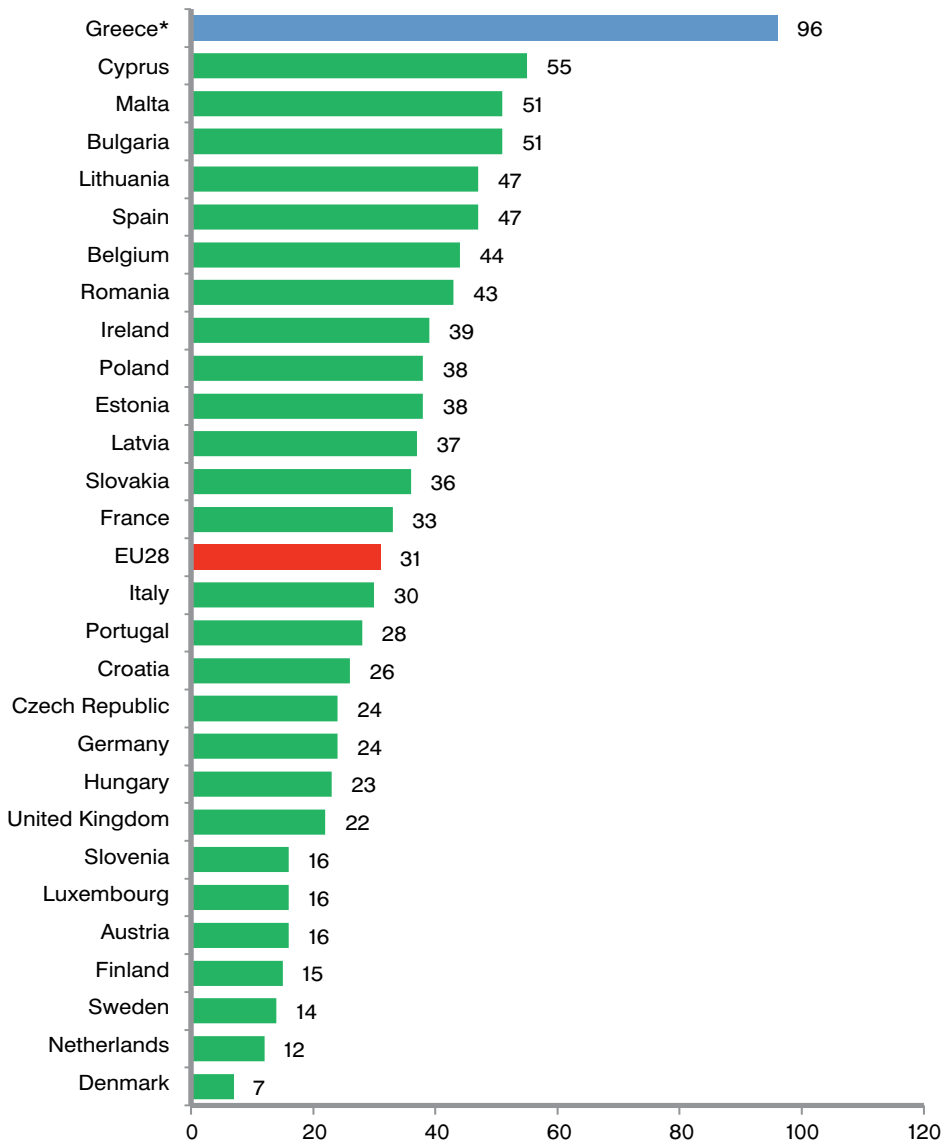
The production and distribution of pharmaceuticals is one of the most dynamic sectors in the Greek industry. Supply chain for pharmaceutical products is comprised of pharmaceutical companies (both manufacturers and importers), wholesalers (both storage and distribution) and pharmacies. More specifically, pharmaceutical products, except products for hospital use only which are provided through sales to hospitals, follow the path: pharmaceutical company - wholesalers - pharmacy.



SOURCE: EL.STAT. EOPYY. PanHellenic Association of Pharmaceutical Wholesalers

With a pharmacy density of 96 pharmacies per 100.000 inhabitants, Greece ranks 1st among EU28, with an average of 31 pharmacies per 100.000 inhabitants.

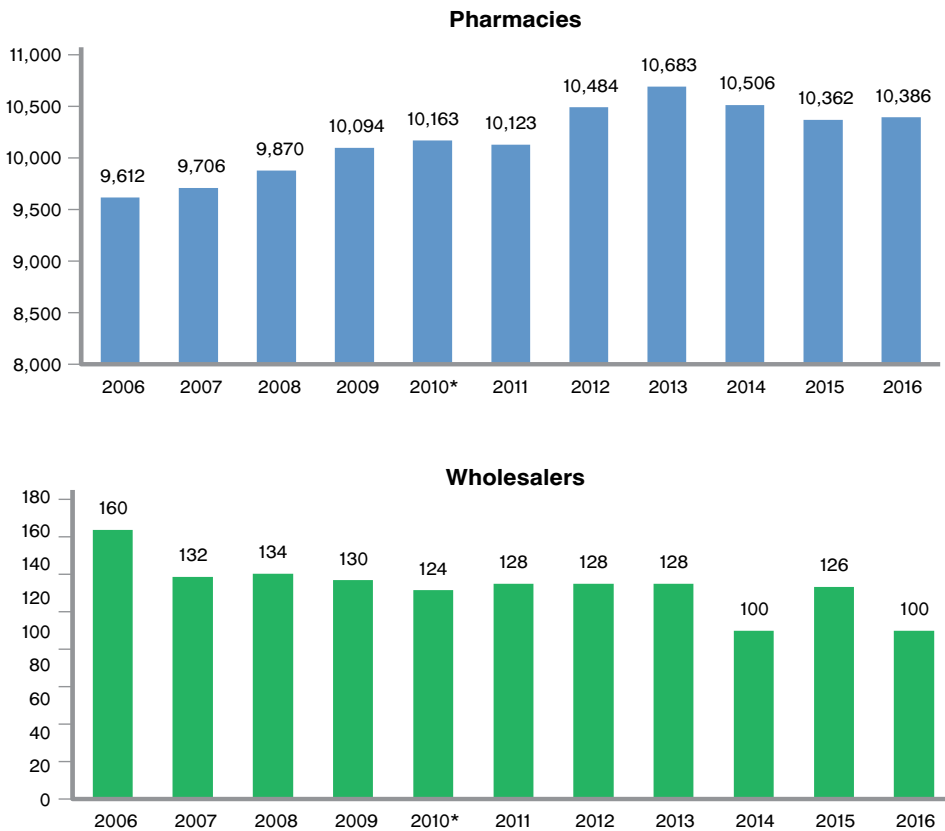
Figure 28: Number of pharmacies per 100.000 inhabitants EU28 (2016)



SOURCE: ABDA. German Pharmacies, Figures Data Facts 2017, EL.STAT., 2017 * Data for Greece come from the latest available ELSTAT data.

In 2016, 10,386 pharmacies operated in Greece, out of which 3,736 pharmacies (36%) were located in the Region of Attiki. The number of wholesalers in 2015 amounted to 100 in 2016 compared to 126 in 2015.

Figure 29: Pharmacies and wholesalers - Greece



SOURCE: EL.STAT.,2017 *Preliminary data

EOPYY PHARMACIES

EOPYY initially operated 5 pharmacies in Attica region and 1 in Thessaloniki, supplying high cost medicines without copayment and without the confirmation of the prescription by the relevant social security fund (except 2 month). Currently, 29 pharmacies of EOPYY are in operation. In other parts of the country, insured citizens can obtain high cost medicines for the treatment of serious diseases (Law 3816/2010) from EOPYY's local health units, after placing an order.

Based on the ministerial decree published in Government Gazette 64/B'/16-01-2014, the list of high-cost, serious diseases pharmaceutical products that fall under the provisions of L.3816/2010 was split into two distinct lists. The first list relates to pharmaceutical products that are only available for hospital use, while the second list includes those pharmaceuticals, which their use begins in the hospital and can be continued on an outpatient setting. EOPYY pharmacies and public hospitals procure products of the first list in hospital price reduced by 5% and the corresponding rebates, while pharmaceuticals of second list followed the way of pricing applied under the provisions set by the Ministry of Health.

By 2015, the majority of high-cost drugs (N.3816 / 2010) was provided by the EOPYY pharmacies and hospital pharmacies.

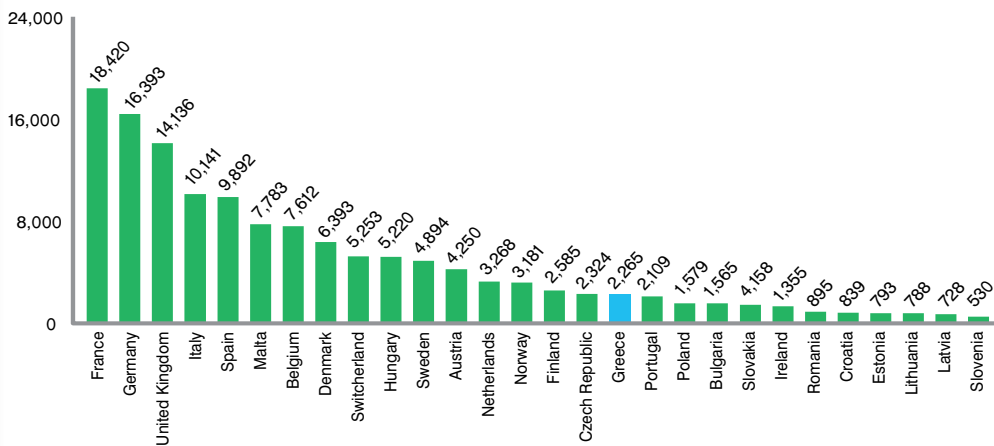
Since January 2016, under the new legislative regulation for hospital clawback (N. 4354 / 12.16.2015, Section D, Article 41), all high-cost medicines that their use is hospital only (Annex 1A) are exclusively administered from pharmacies in public hospitals.

EOPYY pharmacies provide exclusively high-cost drugs belonging to Annex 1B and Annex 1A for use only in specific private clinics.

5.2 RESEARCH AND DEVELOPMENT (R&D)

In Greece, **2,265 clinical studies (1,280 completed)** were conducted up to 2017, number similar to that in countries such as Czech Republic, and less than France, Germany and United Kingdom.

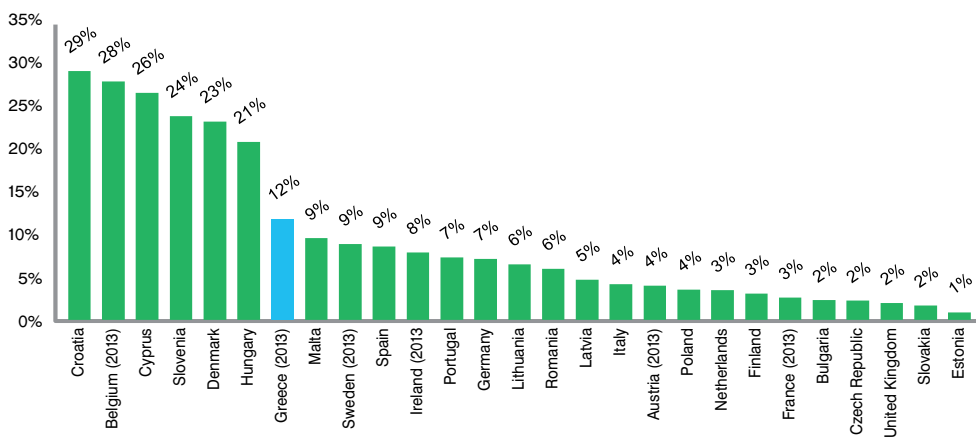
Figure 30: Total number of clinical trials 2017



SOURCE: Clinical trials.gov., 2017

Research & Development expenditure in the pharmaceutical industry accounts for 12% of total R&D expenditure in Greece (2013), share higher than the rest of Southern countries.

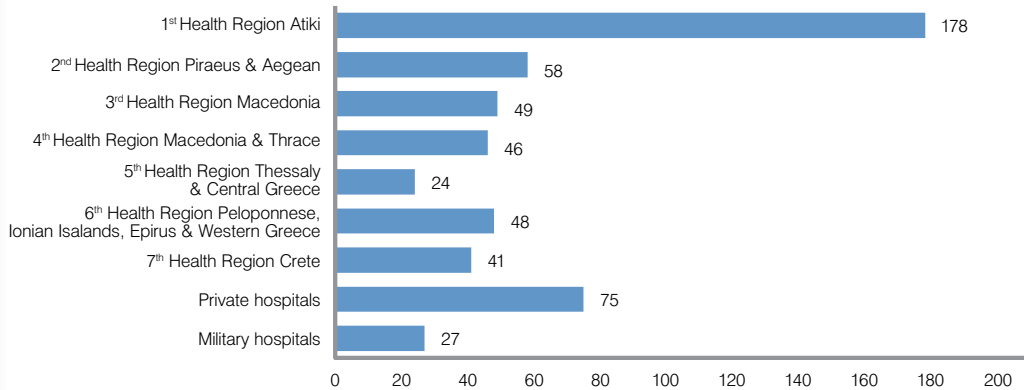
Figure 31: Pharmaceutical R&D expenditure (% of total R&D expenditure)



SOURCE: Eurostat, 2017, data processing IOBE

The largest number of clinical trials in 2015 conducted in the hospitals of 1st Health Region of Attiki (178) and the fewest in the 5th Health Region of Thessaly and Central Greece.

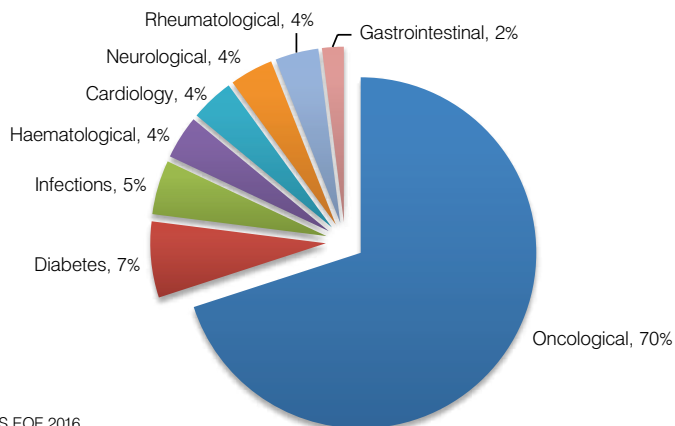
Figure 32: Number of clinical trials per health region (2015)



SOURCE: GREDIS EOF 2016

In 2015, 70% of the clinical trials conducted in Greece concern oncology, while 5% concern infectious diseases.

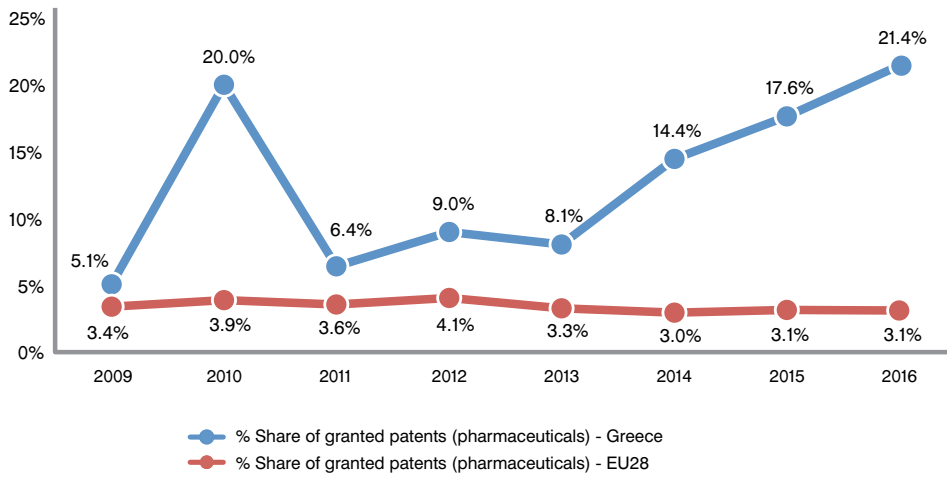
Figure 33: Clinical trials per therapeutic category (2015)



SOURCE: GREDIS EOF 2016

Regarding the share of granted patents in the pharmaceutical sector, the percentage in Greece in 2016 was 21.4% higher than in EU28 (3.1%).

Figure 34: Share of granted patents in the pharmaceutical sector (% total patents) Greece-EU28

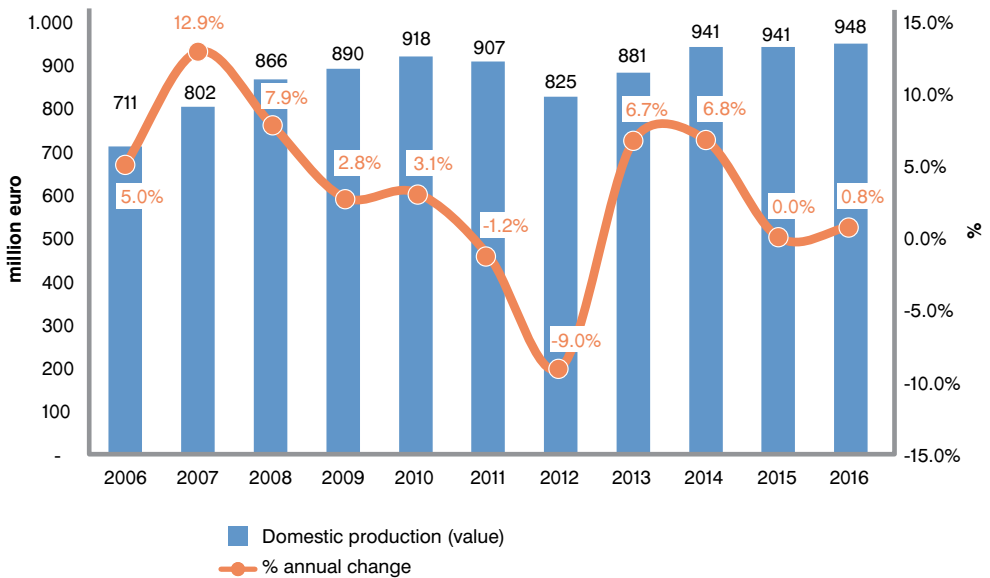


SOURCE: EPO, 2017, data processing IOBE

5.3 DOMESTIC PRODUCTION

According to Prodcom database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece was estimated at €948 mil. in 2016, approximately 0.8% higher than in 2015.

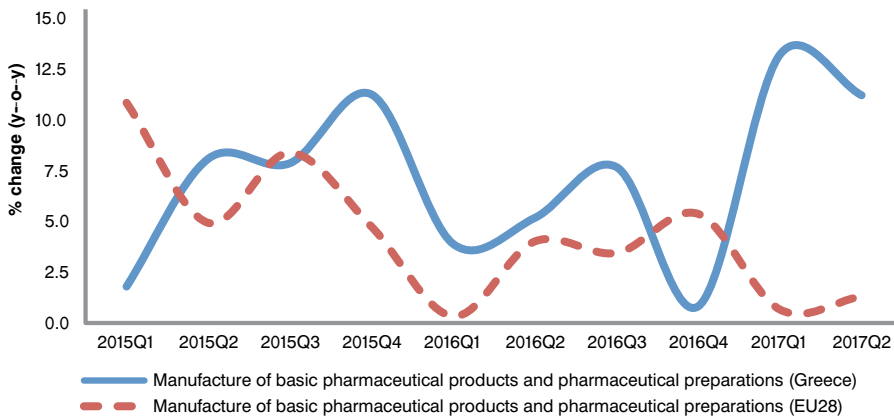
Figure 35: Domestic production of pharmaceutical products (mil.€)



SOURCE: Eurostat 2017, PRODCOM Database. data processing IOBE *Any changes based upon review of data from Eurostat

The industrial index of domestic pharmaceutical production, recorded a significant increase in the first half of 2017, higher than the increase in the first half of 2016, indicating that the value of domestic pharmaceutical production for 2017 will be at higher levels.

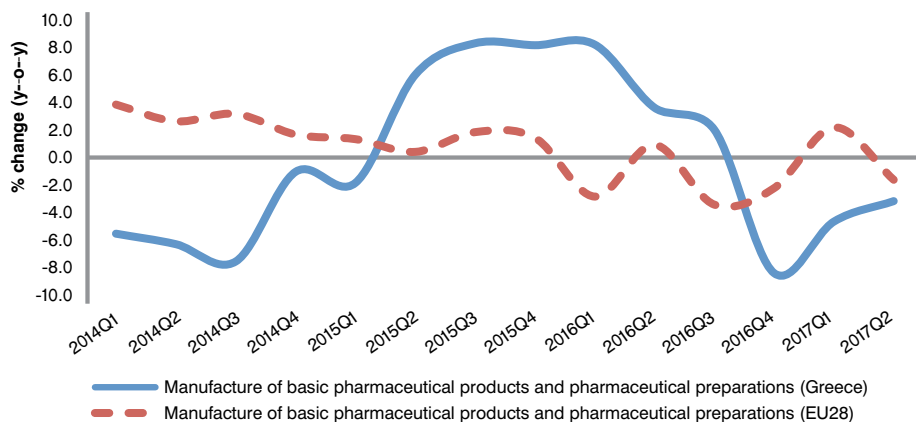
Figure 36: Industrial index of domestic pharmaceutical production (2010=100)



SOURCE: EL.STAT., 2017, seasonally adjusted and adjusted data by working days

Domestic pharmaceutical production recorded a decline since mid-2016, due to a decrease in prices, while in the first half of 2017 the negative turnover sign shrank.

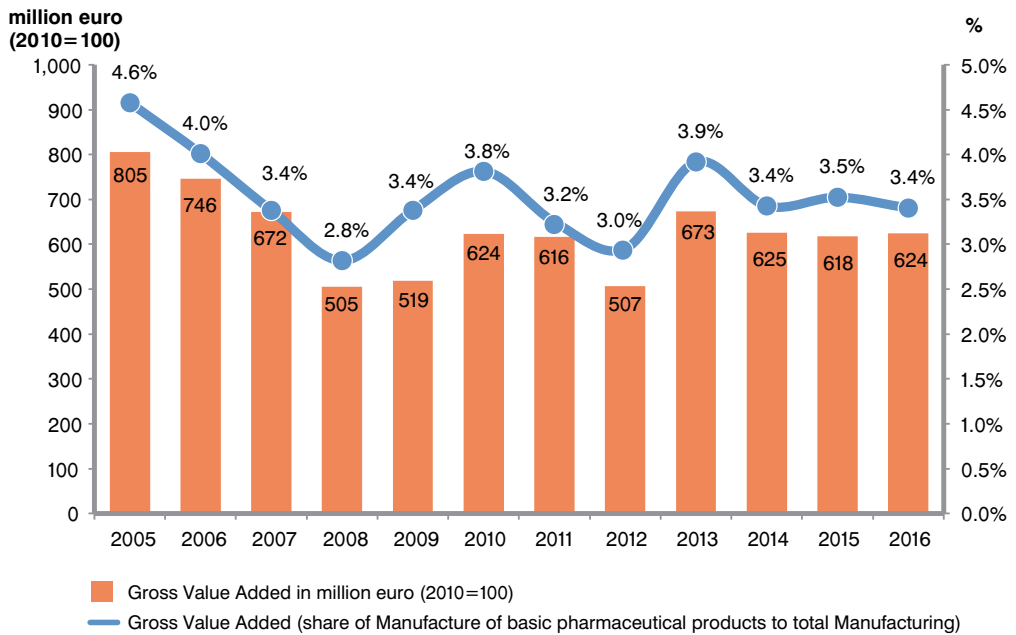
Figure 37: Turnover index in domestic pharmaceutical production (2010=100)



SOURCE: EL. STAT., 2017, seasonally adjusted and adjusted data by working days

The Gross Value Added (GVA) of domestic pharmaceutical production is estimated at €624 mil in 2016, higher by 1% compared to 2015, and amounted with a share of 3.4% in total manufacturing sector. Domestic pharmaceutical production ranked 9th among the 24 sectors of manufacturing for 2016.

Figure 38: Gross Value Added of domestic pharmaceutical production and share in manufacturing (%)

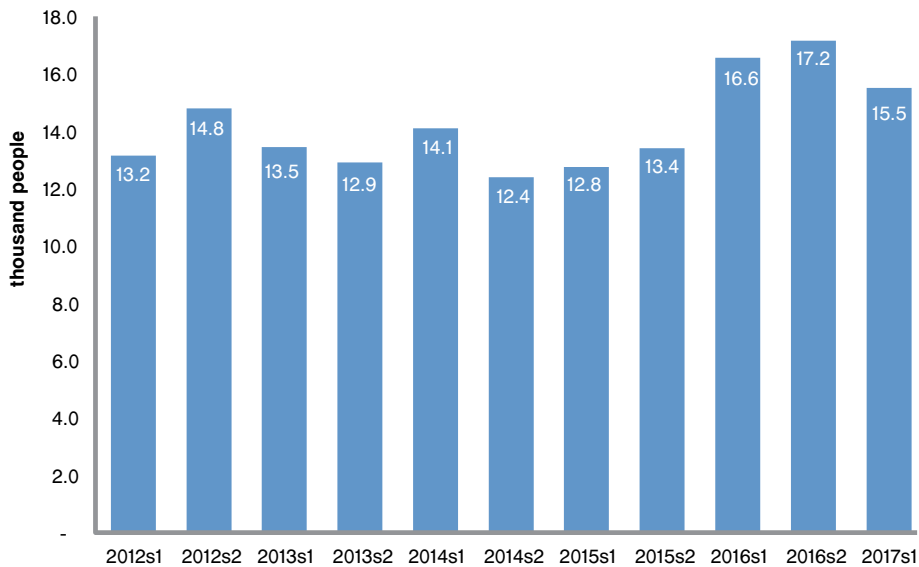


SOURCE: Eurostat.2017, data processing IOBE*Any changes based upon review of data from Eurostat* C 21: Manufacture of basic pharmaceutical products and pharmaceutical preparations include only the companies active in the production of medicines and pharmaceutical preparations. In C 21 manufacturing companies are not included firms that belong to subsector 46.46 Wholesale of pharmaceutical products.

5.4 EMPLOYMENT

According to Eurostat, 15.5 thousand people were employed in pharmaceutical production in Greece in the first semester of 2017, demonstrating a decrease of -6.3% compared to the first semester of 2016.

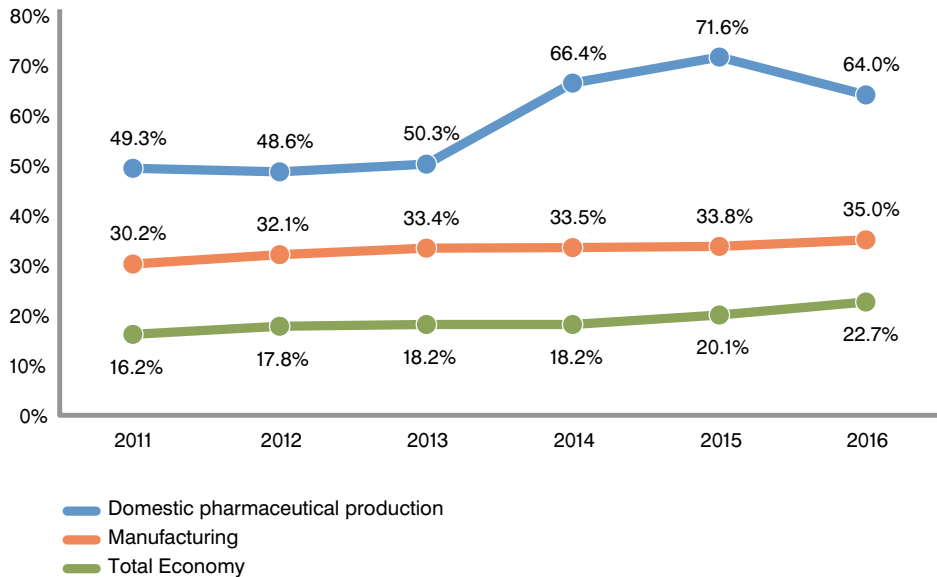
Figure 39: Employment in domestic pharmaceutical production (thousand people)



SOURCE: Eurostat, 2017, Labour Force Survey, 2017, data processing IOBE * s1 refers to the first semester of every year and s2 refers to the second semester. ** Employees in the wholesale sector of the wider health sector are not included

At the same time, according to the International Standard Classification of Education (ISCED) for 2016, the educational background of people working in the pharmaceutical industry was very high, with 64% of total employees in pharmaceutical production with university education compared to 35% in the manufacturing and 22.7%, in the total economy, indicating the high educational training of the employees in the pharmaceutical industry. This difference shows the importance of domestic pharmaceutical production as a preventive sector in the brain drain.

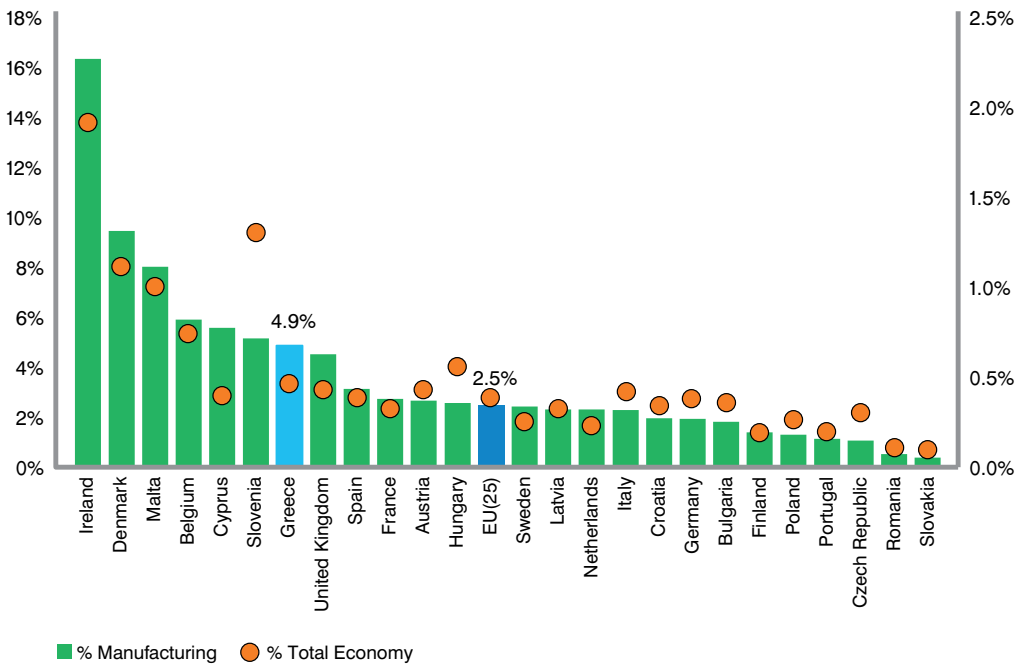
Figure 40: Number of employees with tertiary education in domestic pharmaceutical production (%)



SOURCE: EL.STAT. 2017, Employees Tertiary Education of total employment International Standard Classification of Education (ISCED 2011)

In 2016, employment in the pharmaceutical sector represents 0.5% of total employment of the Greek economy, while this share increases to 4.9% with regards to employment in the manufacturing overall. The share of manufacturing is higher than the respective average in EU25 (2.5%).

Figure 41: Employment in the production of pharmaceutical products (% manufacturing and economy) EU25 (2016)



SOURCE: Eurostat, Labour Force Survey, 2017, data processing IOBE

An important measurement for employed people is the recording time in Full Time Equivalent (FTE), by calculating total employment assuming that all workers are employed full-time. According to the available data, pharmaceutical industry recorded a decline of employment in FTEs by -2.8% during 2010-2016 compared to total manufacturing (-25.5%), indicating that employment in pharmaceutical sector shows inflexibility. Simultaneously, total wage cost decreased by -7% compared to much larger decline in manufacturing (-36.4%). At the same time, the average hourly wage stood at €10.5 for pharmaceutical industry compared to €6.7 in total manufacturing and €5.3 for the total economy.

Table 1: Change in employment and wages 2010-2016

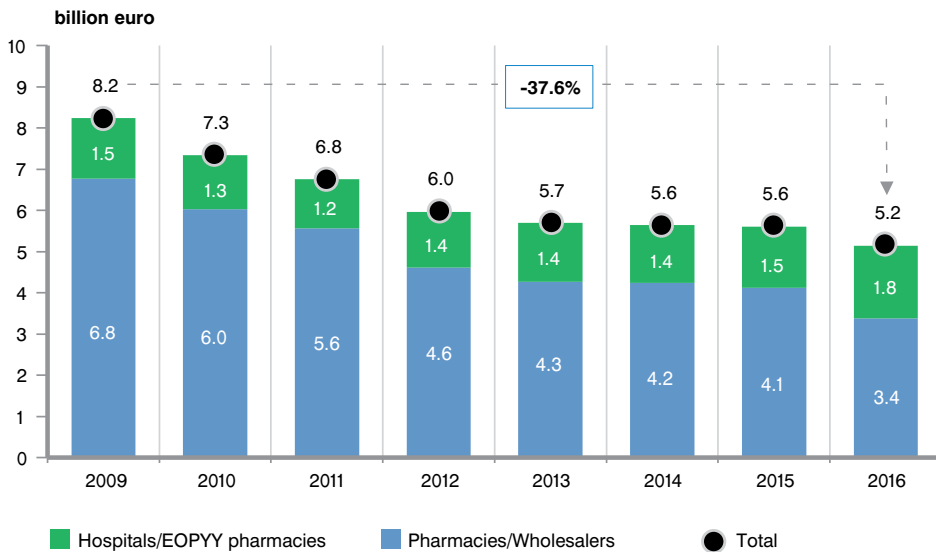
	Employment % change (FTE)	Compensation of employees	Average hourly wage (2016)
Total Economy	-12.8%	-30.9%	5.3 €
Manufacturing	-25.5%	-36.6%	6.7 €
Domestic pharmaceutical production	-2.8%	-7.0%	10.5 €

SOURCE: Eurostat, National Accounts, 2016, data processing IOBE

5.5 SALES

Sales of pharmaceutical products to pharmacies & wholesalers amounted to €3.4 bil. in 2016, showing a reduction of -18.1% compared to 2015. On the contrary, sales to hospitals & EOPYY pharmacies amounted to €1.8 bil. in 2016 presenting an increase of +19.2% compared to previous year. Approximately, 65.6% of total sales were supplied to wholesalers and private pharmacies, while the remaining 34.4% to hospitals and EOPYY pharmacies.

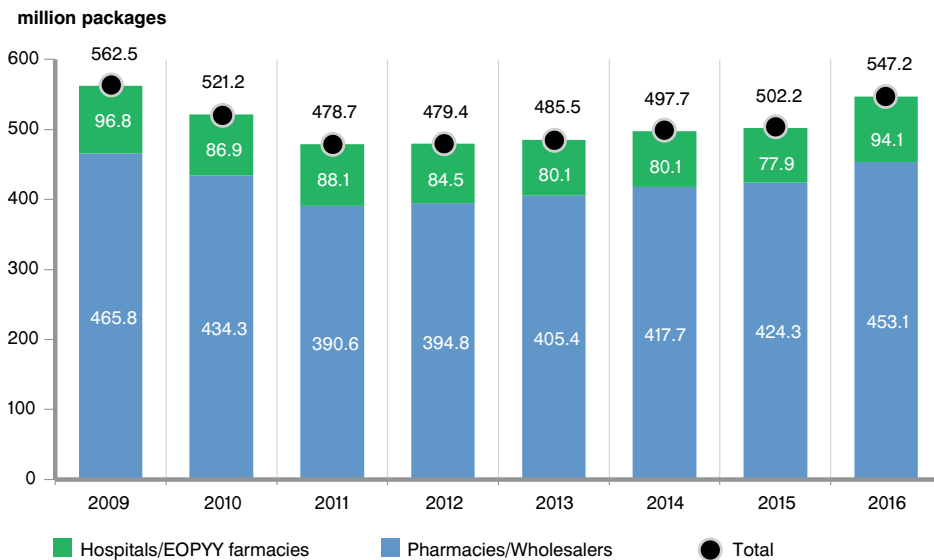
Figure 42: Sales of pharmaceutical products in values (bil. €) Greece



SOURCE: EOF 2016 (Pharmacies/Wholesalers at retail prices and Hospitals at hospital prices) Total pharmaceutical sales recorded monthly by the National Organization of Medicines (EOF) and include pharmaceutical sales by pharmaceutical companies to hospitals (at hospital prices) and Wholesalers / Pharmacies (at retail prices). Sales also recorded in terms of number of packages. Parallel exports in 2014 were €306.7 mil. and are included here.

Regarding the number of packages, an increase of +9% was recorded in 2016 compared to 2015 (547.2 mil. packages). On the contrary, an increase of +6.8% in pharmacies/wholesalers and an increase of 20.7% in hospitals/EOPYY pharmacies was depicted.

Figure 43: Sales of pharmaceutical products in volume (mil. packages) - Greece

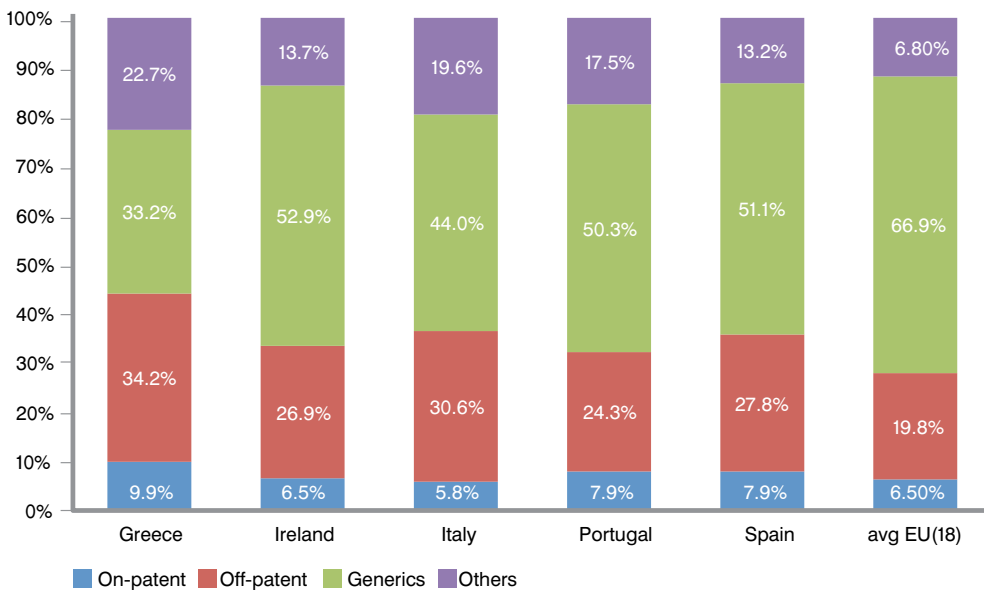


SOURCE: EOF 2017 *Possible smaller packaging replacements

Pharmaceutical products can be classified according to their patent protection status. According to IMS (MAT03/2017), the penetration rate of patent protected medicinal products (on patent) in terms of volume account for 9.9% of the market, which is higher than the average of EU18 (6.5%) which can be partly justified by their significantly lower prices in Greece compared to EU18 countries (€0.88 per unit on average compared to €1.94).

Respectively, the market share of non-protected pharmaceutical products amounted to 67.4% (off-patent 34.2% & generics 33.2%). It is worth noting that the penetration rate of off-patent is higher than the average of EU18 (19.8%), while penetration rate of generics is much lower than the average of EU18 (66.9%).

Figure 44: Penetration rate of pharmaceuticals in volume based on patent status EU18 (2017)



SOURCE: IMS. MIDAS 12/2016. Note: Includes only retail sales for all countries. * Note: Only retail sales data for all countries are included.
** The EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, the Netherlands, the UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary Poland and Slovakia

According to IMS (MAT03/2017), penetration rate in volume for off patent and generic products is partly justified by significantly lower prices for off patent products in Greece compared to the average of EU18 (€0.25 per unit compared to €0.31) and by slightly higher prices for generic products in Greece compared to the average of EU18 (€0.18 per unit compared to €0.12).

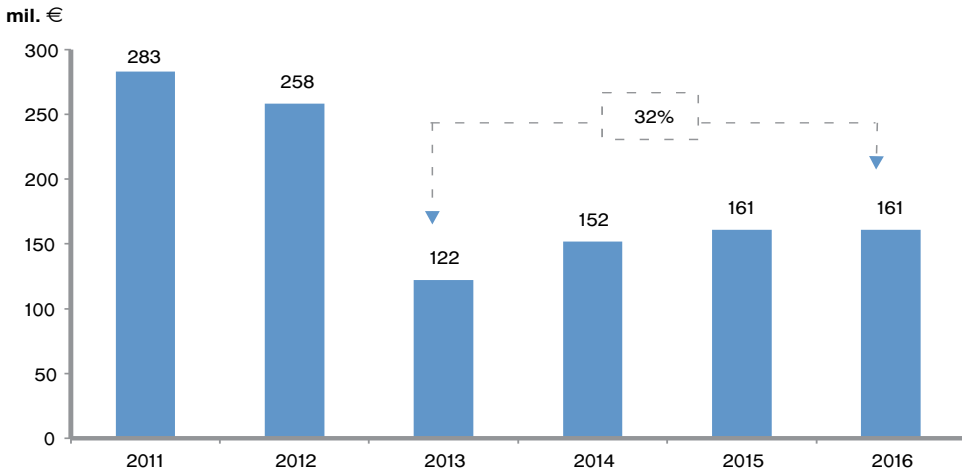
Figure 45: Pricing of pharmaceuticals in values (e per unit) EU18 (2017)



SOURCE: IMS. 12/2016 Note: only retail sales are included for all countries; EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, Netherlands, UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary, Poland, Slovakia

The market of OTC followed an upward trend from 2013 onwards from €122 mil. in 2013 to €161 mil. in 2016, an increase of 32%.

Figure 46: OTC sales in value (mil. €)



SOURCE: AESGP, 2017 *Note: Depending on the source of information used, there may be deviations over EFEX-AESGP data.

The General Distribution Medicines (GEDIFA), a subset of O.T.C. (216 of the total 1.582 O.T.C), are available outside pharmacies and concern analgesics, antipyretics, antipruritic, topical medications, laxatives (to treat constipation) and mouthwashes. Of the self-medication products, analgesics, cough and cold products, digestive products, dermatological products and vitamins recorded the largest sales.

Table 2: Sales self-medication products (mil. €)

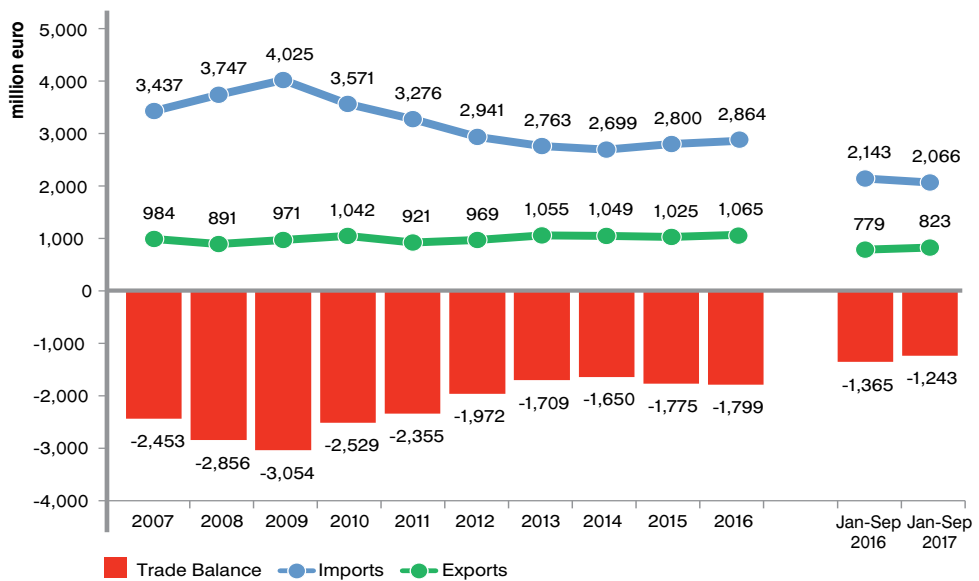
Category	2013	2014	2015	2016	%16/15
Analgesics	59	68.3	77.9	64.5	-17.2%
Cough & Cold	66.3	72.5	80.3	65.4	-18.6%
Digestives & Intestinal	22.5	26	30.4	28.4	-6.6%
Skin Treatment	32.1	33	37.4	31.6	-15.5%
Vitamins & Minerals	62.1	76.2	84.7	66.9	-21.0%
Rest categories	81.1	64.4	23.9	82.6	245.6%
Total	323.1	340.4	334.6	339.4	1.4%

SOURCE: AESGP, 2017 Note: Any changes based upon review of data from EFEX-AESGP

5.6 EXTERNAL TRADE

Imports and exports of pharmaceutical products amounted to €2.9 bil. and €1.0 bil. in 2016, increased by 2.3%, and 3.9% respectively, resulting on a deficit of -€1.8 bil. In the first 9 months of 2017, an increase of 5.7% in exports and a decrease of 3.6% in imports were recorded. Pharmaceuticals exports accounted for 4.2% of total Greek exports in 2016 and among manufacturing sectors (excluding mineral oils), pharmaceutical industry ranks 4th in 2016 with 5.0% of exports of total manufacturing. It is worth mentioning that based on data from the Panhellenic Exporters Association in 2016 medicinal products are the 2nd exported product in terms of value after mineral oils based on the Standard International Trade Classification (SITC) in 5-digit resolution.

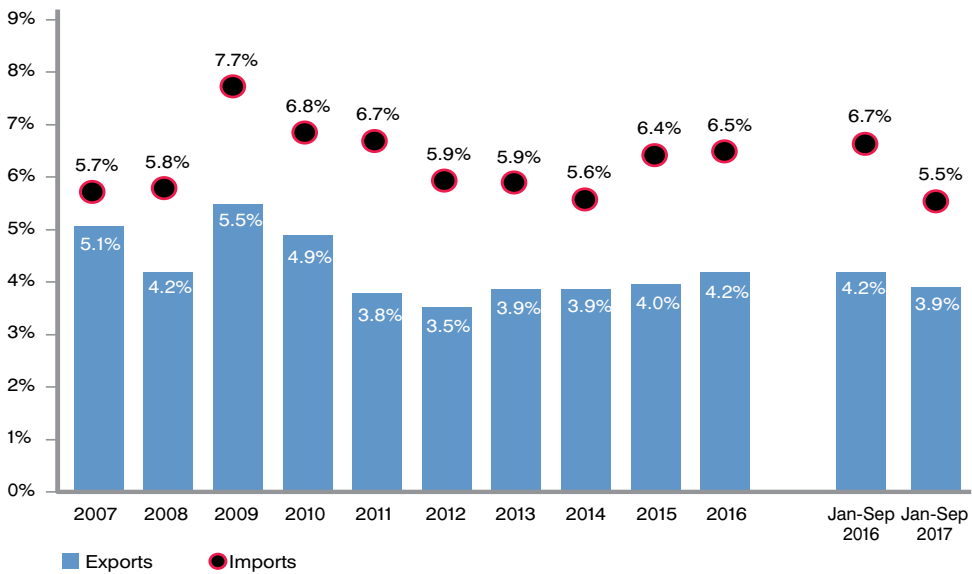
Figure 47: Evolution of pharmaceutical trade balance (mil.€)



SOURCE: Eurostat International trade, EU Trade Since 1988 By CN8, data processing IOBE

Regarding the most important trading partners in the category of pharmaceuticals, on the side of imports is Germany (27%), France (10.7%) and Switzerland (10%), while on the side of exports is again Germany (18.8%), United Kingdom (14.8%) and Cyprus (7.9%). It should be noted that the Greek pharmaceutical industry imports from 61 countries and exports to 141 countries.

Figure 48: Share of pharmaceutical exports-imports (% of total exports-imports) Greece



SOURCE: Eurostat International trade, EU Trade Since 1988 By CN8, 2017, data processing IOBE

5.7 PRICING OF PHARMACEUTICALS

Prices of medicinal products in Greece are set based on international reference pricing (IPR) system. Specifically, as set by the Law 4213, Chapter 4, art.22, prices for medicinal products are set based on the average of the 3 lowest prices in EU28. The above provisions are specified by ministerial decisions. During 2017 there were not any significant changes in price setting.

Ministerial decision **GG3890/B/02.12.2016**, as described below, sets the provisions under which pricing of pharmaceutical products is currently set.

Maximum ex-factory price for **on-patent** products is based on the average of the 3 lowest prices (9-digit code EOF) in EU 28, where reliable data are published.

In order for a medicinal product to be priced for the **first time**, it needs to have been priced in at least three EU countries. In the absence of the same medicinal product in three EU countries, it will not be priced in Greece. Only **orphan medicinal products** may be priced even if prices are available in only two EU countries.

Medicinal products that have no sales during the last 3 years from the date of price approval or have no sales for three consecutive years after their first price list, will not be priced regardless of whether the license is revoked declaratory by EOF.

The maximum ex-factory price of off-patent products (those products that lost their patent protection), for which the first generic was introduced, is automatically reduced either by 50% of the last price the product held under when patent protection (wholesaler price is price when the first generic was introduced) or according to the average of the 3 lowest prices in EU, considering the lowest between the two options above, and by no means lower than the lowest price in EU.

For off-patent products for which there is no generic in the market during the last 12 months based on EOF sales, or there are not any similar products based on Article 10 of this ministerial decision (produced in Greece), the average of the 3 lowest prices in EU applies.

The price of generic products, regardless of their approval date, retain 65% of the resulting price of the reference off patent, as it is formed based on the aforementioned.

In order to promote the use of less expensive treatments as well as for the protection of public health, and in order not to undermine the adequacy of those products, limits in price reductions of off patent products, and respectively for their generics, are defined in a ministerial decision.

Price reductions resulting from price revision will not be greater than 10% of the wholesaler price. If the resulting price of the generic after the end of this process, is greater than the price of the off patent product, the protection of 10% will not apply and the price of generics will be determined at 65% of the resulting price of the off patent product.

The ex-factory price of biologics and bio-similar products is defined as the average of the 3 lowest prices in EU.

Exceptionally prices of blood derivatives may not be less than the average of the 3 lowest prices in EU. For public health reasons, blood products and vaccines are excluded from price revision. Furthermore, medicines available exclusively abroad (for export) are also excluded from price revision. Prices of hybrid products should not be greater than the prices of reference products belonging to the same ATC5 and have similar pharmaceutical form and content. Also, for generic drugs with a retail price of more than €12, dynamic pricing is applied.

Prices of medicinal products produced exclusively in Greece that cannot match with the pharmaceutical form or content of a off patent product in the domestic market (domestically produced) are set based on cost estimates, including production and packaging costs and administration - sales – proliferation costs, as determined by the relative tables calculated based on the average costs of the industry. The prices of medicinal products produced exclusively in Greece should not be greater than the prices of off patent products belonging to the same ATC5 and have a similar pharmaceutical form and content.

For the medicinal products that have undergone R&D on their active substance or their pharmaceutical form, signed as Greek patented invention, and which have undergone clinical pharmacokinetic studies and are authorized by EOF, the value of R&D investment on the active substance or the active substance or pharmaceutical form as well as the expertise, will be also considered in shaping the aforementioned cost estimate.

The maximum net profit rate is set at 8.5% and is calculated on the total cost excluding depreciation, interest and profit to third parties for jobbing.

With Law 4472/2017 and Ministerial Decision 38152 / GG 1761 / B / 22.05.2017 the retail price and the maximum hospital price of OTC products is determined, as well as their distribution. According to the provisions of the law, the indicative retail price:

- a) The average of the three lowest prices of EU member states where price was found.
- b) If it is not possible the pricing of the OTC product, the product take price according to the average of the prices in the two Member States where the price was found,
- c) If the OTC product is priced in only one Member State, then the lowest price shall be taken between the applicable price, and the price in the other Member State, otherwise it shall be taken the price of that Member State,
- d) If the previous case cannot be applied, then the OTC product is priced based on the correlation with similar active substances and pharmaceutical formulations in Greece. Correlation can also be achieved with similar prescribed pharmaceutical products.

“An indicative retail price is defined as the base price obtained under the preceding paragraph, plus 30% plus the estimated VAT. The retail selling price is indicated in the decision that it is not compulsory for pharmaceutical companies, wholesalers, pharmacies, or other retailers of these products.

PRICE DEFINITIONS

Maximum Wholesaler Price: price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the wholesaler, which is calculated as a percentage on the maximum ex-factory price. Gross profit margin (mark-up) a) for all medicinal products reimbursed by social security funds is set as a percentage of 4.9% on the maximum net ex-factory price (up to €200) and 1.5% on the maximum net ex-factory price (>€200) b) for non-prescription medicinal products (OTC) as a percentage of 7.8% on the maximum net ex-factory price and c) for medicinal products that belong to par.2, art.2, L3816/2010 as a percentage of 2% on hospital price. The latter is called as Special Wholesaler Price.

Maximum Retail Price: price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy as set out in the respective ministerial decree and the applicable Value Added Tax (VAT 6.0%). In particular, for pharmacies the mark up is determined as follows: a) 35% on the wholesale price for non-prescription medicinal products (OTC) b) 35% on the wholesale price for non-reimbursed prescription products c) for reimbursed products (see Table 6) and for products with price > €3.000 is set a percentage of 2%. (Table 4).

Ex-factory price: price at which medicinal products are sold by the marketing authorization holders (MAHs) to wholesalers and is calculated based on the wholesaler price reduced a) for prescription reimbursed medicinal products by the Social Insurance Funds with price up to 200€ by 4.67% and with a price exceeding €200,01 by 1.48%, b) for prescription medicinal products which are not reimbursed by the Social Insurance Funds by 5.12%, and c) for non-prescription (OTC) medicinal products by 7.24%.

Maximum Hospital Price: price at which medicinal products are sold by the Marketing Authorization Holders to the State, State hospitals, Social Care Units, EOPYY pharmacies, public law legal entities referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with hospital pharmacy. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8.74%.

Profit margins of wholesalers vary depending on the reimbursement status of each product that is, on whether the product belongs in the positive, negative, OTC list or if they fall under L.3816/2011 provisions and its relative wholesaler price. Also, pharmacists profit margins vary according to the wholesaler price of each product. For medicines belonging in the positive list (and therefore reimbursed by the social security funds) profit margins and the price structure are set as follows:

Table 3: Mark-up in the pharmaceutical supply chain 2016-2017

	Reimbursed Products up to 200€	Reimbursed Products > 200.01€	OTC	Negative list products
Wholesalers (over ex-factory)	4.9%	1.5%	7.8%	5.4%
Pharmacies	(Table 4)	(Table 4)	35%	35%

SOURCE: M.D. (3890/2.12.2016)

Table 4: Percentage of profit (mark-up) pharmacies

Wholesale price (€)	Percentage mark-up pharmacies
0 - 50	30.00%
50.01 - 100	20.00%
100.01 - 150	16.00%
150.01 - 200	14.00%
200.01 - 300	12.00%
300.01 - 400	10.00%
400.01 - 500	9.00%
500.01 - 600	8.00%
600.01 - 700	7.00%
700.01 - 800	6.50%
800.01 - 900	6.00%
900.01 - 1000	5.50%
1000.01 - 1250	5.00%
1250.01 - 1500	4.25%
1500.01 - 1750	3.75%
1750.01 - 2000	3.25%
2000.01 - 2250	3.00%
2250.01 - 2500	2.75%
2500.01 - 2750	2.50%
2750.01 - 3000	2.25%

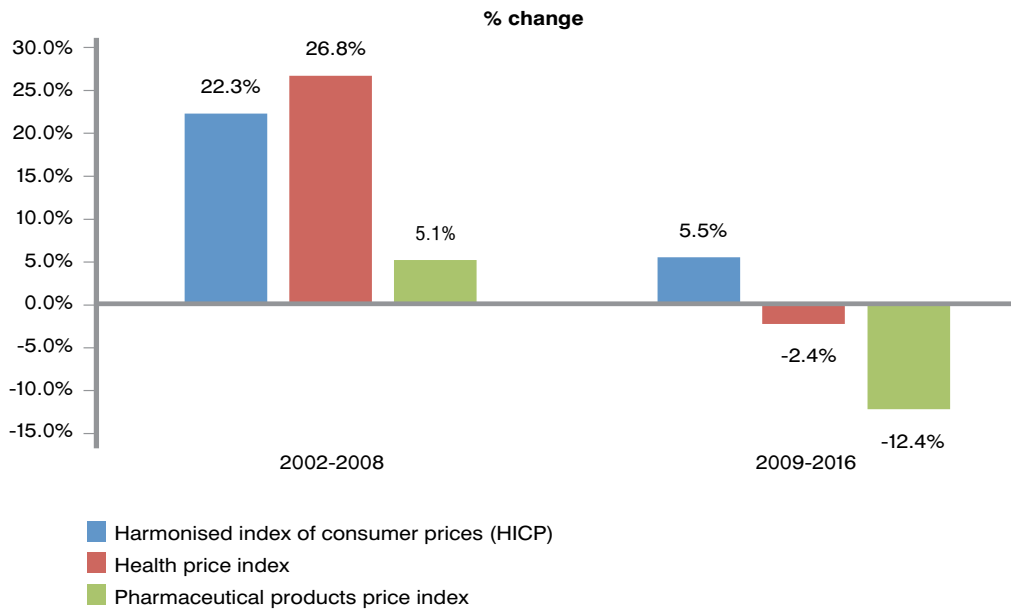
SOURCE: M.D. (3890/2.12.2016)

Mark-up margins mentioned above are the maximum margins allowed in the case of OTC for wholesalers and pharmacists, who may voluntarily provide these products in lower prices as long as it is recorded in the respective invoice.

Additionally, these margins are applied to all reimbursed products sold in private pharmacies including products of L.3816/2010 list. When the latter are directly sold by private pharmacies and the respective cost is not reimbursed by EOPYY or any other SSF, pharmacist margin is set based on the table above and for products with wholesaler price greater than €3.000 at 2%.

The period between 2002 and 2008, prices increased by 5.1% presenting the lowest increase between health index (+26.8%) and between categories of goods (22.3%), while between 2009 and 2016 the pharmaceutical price index decline with greater intensity (12.4% reduction).

Figure 49: Annual change (%) of HCIP by category (2015=100)



SOURCE: Eurostat. Harmonised Indices of Consumer Prices (HICP), 2017 data processing IOBE

5.8 REIMBURSEMENT OF PHARMACEUTICALS

Below are the most important legislative changes for pharmaceutical products in Greece.

As defined in the ministerial decision published in **GG1144 / 05.06.2014**, the reference price is calculated as the weighted average of the lowest cost of daily treatment of generics that account for 20% of market sales during the last six months prior to the calculation of prices. Sales are based on EOPYY expenditure.

In cases where a patient chooses a medicinal product with retail price equal to the reimbursement price, then he only pays the statutory co-payment (0%, 10%, or 25%). In cases, where the patient decides to choose a product where retail price is greater than the reimbursement price, then he must pay the set co-payment and additionally the full difference between these prices. Finally, when the retail price is lower than the reimbursement price, up to 50% of the difference between them is deducted from the set co-pay. Based on the ministerial decision published in GG335/02.16.2016, the maximum amount a patient can pay on top of the set co-pay cannot exceed €20 per pack.

According to **Law 4772/2017 (Gazette 74 / A / 19.05.2017)**, a classification system for pharmaceutical products is applied for the compilation, revision and completion of the catalogue according to the Anatomic Therapeutic Chemical Classification (Anatomic Therapeutic Chemical Classification- ATC) of the World Health Organization (WHO) and introduces a reference price system (RPS) by category of pharmaceutical products. EOPYYY and SSFs reimburse for medicinal products that are in a period of protection of their active substance data and have been authorized in accordance with the national or decentralized procedure or the mutual recognition procedure or the centralized procedure of **Regulation 726/2004 / EC L 136**, if the following conditions are met cumulatively: (1) Reimbursement to at least two-thirds (2/3) of the Member States of the European Union, the states in which they circulate may not be less than nine (9) and at least half of these countries included in the following specifically mentioned Member States that have a Health Technology Assessment Mechanism for human medicines, namely: Austria, Belgium, Great Britain, France, Spain, the Netherlands, Portugal, Sweden and Finland; and (2) They are receiving a positive assessment by the Commission, by criteria of health technologies applied in combination, which are: a) Unfulfilled medical (b) the added therapeutic value of the medicinal product under assessment in relation to existing therapies; (c) the reliability and representativeness of the clinical documentation; and (d) the cost-benefit or effectiveness after taking into account the financial implications of public pharmaceutical expenditure in relation to the pharmaco-epidemiological and pharmaco-economic data of the country. If the Commission considers that a product does not meet the last cost-benefit criterion, it shall refer it to the Negotiating Committee referred to in Article 3 of Law 4208/2013 (A252) and issue the notice to the Minister only after the successful conclusion of the negotiation process. The Committee shall decide on the therapeutic indications, treatment lines, strengths and packings for which the positive list medicinal products are reimbursed after their evaluation under these criteria. In order to reimburse for the therapeutic indication of a medicinal product, additional and different from one or more of the therapeutic indications for which it is included in the positive list, a prior request from the Marketing Authorization Holder is required

and its assessment by the Commission based on the above criteria. By decision of the Minister of Health, following the opinion of the Committee, medicinal products which have been authorized as orphan medicinal products or medicinal products for the treatment of Mediterranean anemia only if they are covered by international clinical protocols and receive a positive evaluation. By decision of the Minister of Health, following the opinion of the Committee, which is published in the Government Gazette, it is posted on the website of EOF, and cannot be issued before 1.6.2018, the abovementioned list of EU countries may be revised, which have a Health Technology Assessment mechanism.

Within fifteen (15) days of the publication of the Ministerial Decision, the marketing authorization holders (MAHs) whose medicinal products: (i) have been included following a request for inclusion in the positive list of prescription but they have objections to the way their products are ranked in the reference price system; or (ii) they have not been included in the positive list after a request for non-inclusion in the positive list of prescriptions due to non-acceptance of the form or (iii) they have not been included in the positive list of prescriptions and at the same time do not appear on the negative list of prescription drugs referred to in subsection (a) or this paragraph; or (iv) they have been included in the negative list in the subparagraph or in this paragraph, treatment before them of the Special Committee. The application shall be accompanied by supporting evidence and the applicants shall be invited to make oral submissions before the Special Committee. Within thirty days of the submission of the application, the Special Committee of the positive list in paragraph (c) of this paragraph, if, on the basis of the objective criteria laid down in the applicable provisions, it considers the claim to be well founded, it shall establish a supplementary list, approved in the manner specified in this paragraph. Applications rejected or accepted must be fully justified by the Special Committee.

Table 5: Interventions and policy measures Pricing, Reimbursement & Rebate 2017

Ministerial Decision	Gazette Government	Subject
M.D. 95830	4617/B/28.12.2017	New way calculation of hospital clawback
Law 4509	201/A/22.12.2017	Increase in hospital pharmaceutical expenditure
M.D. 87526	4506/B/20.12.2017	Positive List
M.D. 88548	4313/B/11.12.2017	Clawback and rebate
Corrections of M.D. /77022	4126/B/28.11.2017	Positive List 28.11.2017 (corrections)
M.D. /77022	3823/B/31.10.2017	Approval of the positive list
M.D. /74015	3805/B/27.10.2017	Revision of the Lists for the Treatment of Serious Diseases
M.D. 63406	3197/B/12.09.2017	Applying a closed budget for hepatitis C (direct antivirals) medicines
M.D. 65623	3028/B/01.09.2017	Approval of the positive list
M.D. 55332	2560/B/24.07.2017	Approval of the positive list
M.D. 49910	2296/B/06.07.2017	Amendment of the positive list
M.D. 50389	2254/B/30.06.2017	Clawback mechanism of pharmaceutical expenditure for years 2016, 2017 and 2018"
M.D. 43125	1984/B/08.06.2017	Details and procedure for calculating and offsetting the deduction granted to pharmacies for generics
M.D. 39260	1863/B/26.05.2017	Approval of the positive list
M.D. 38152	1761/B/22.05.2017	Provisions for the procedure and procedure for setting the retail selling price and maximum hospital price and disposal for 'non-prescription medicines'
Law 4472	74/A/19.05.2017	measures for the implementation of budgetary targets and reforms, social support measures and labour regulations
M.D. 27617	1469/B/28.04.2017	Revision of the Lists for the Treatment of Serious Diseases
M.D. 994	718/B/08.03.2017	Approval of the positive list
M.D. 9941	479/B/17.02.2017	Approval of the positive list
M.D.11601	445/B/15.02.2017	Pricing Arrangements

STATE'S DEBT TOWARDS PHARMACEUTICAL FIRMS

The Hellenic Association of Pharmaceutical Companies (SFEE) collects and records data related to State's debts to its member companies (on a voluntary basis). Below an overview of total receipts, sales invoices and debts until 31.12.2017 only for the pharmaceutical industry are presented. The data collected refer to invoices in the period described above.

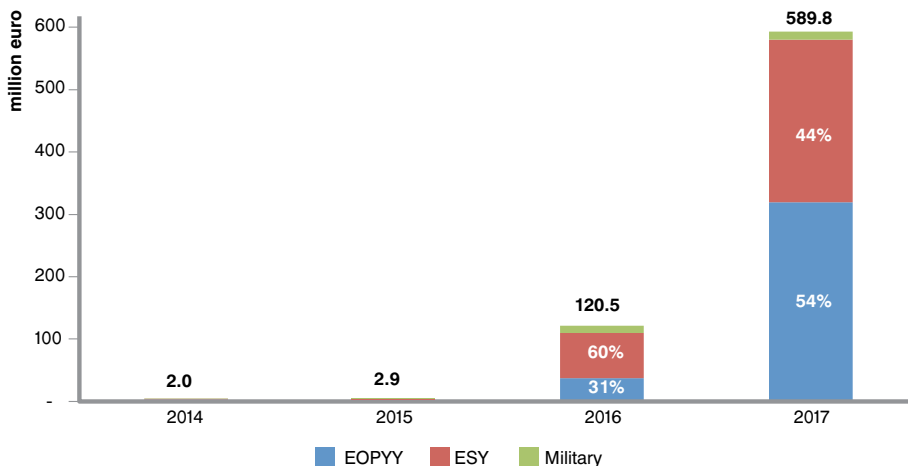
Data for outstanding debts from NHS hospitals, EOPYY, and Military hospitals also constitute the largest part of health expenditure.

Specifically, findings show that:

For 2014 and 2015, the amount of government debts to SFEE member companies for invoices until 31.12.2017 amounted to **€2.0 mil. and €2.9 mil.**, respectively. For 2016, the amount of government debts to SFEE member companies for invoices until 31.12.2017 amounted to **€120.5 mil.**, of which 31% are for EOPYY and 60% for NHS (the remaining 10% in military hospitals), while for 2017 debts amounted to **€589.8 mil.**, 54% of which are for EOPYY and 44% for NHS (the remaining 2% for military hospitals).

More generally, there is a relatively stable repayment of the outstanding debts of the State to pharmaceutical companies. As, pharmaceutical companies are significantly behind in settling state debts both standalone and comparative to other providers, a stable repayment policy must be established directly so as to avoid inability of pharmaceutical companies to support both the market and their businesses.

Figure 50: State debts evolution towards SfEE member companies' per year (€ mil.)



SOURCE: SFEE

7.1 SYSTEM OF HEALTH ACCOUNTS (SHA)

In 2012, the Hellenic Statistical Authority (EL.STAT.) in collaboration with the Center for Health Services Management and Evaluation of the Nursing Department of the University of Athens and Dr. Markus Schneider (BASYS, Germany) published for the first time statistics on National Health Expenditures (both public and private) based on the System of Health Accounts (SHA) of the Organization for Economic Cooperation and Development (OECD). The Hellenic Statistical Authority (EL.STAT.) publishes every year statistical data for the Funding on Health Expenditures at national level based on the new System of Health Accounts manual SHA 2011 of the OECD, against SHA 1.0 that used for earlier data.

Based on article 6 of the European Regulation (EU) 1338/2008 of the European parliament re matters of public health and the respective under voting Implementation Regulation and in cooperation from OECD & WHO the new compilation of SHA data was created. As such, ELSTAT was obliged to communicate SHA data to Eurostat and to International Organizations (OECD and World Health Organization) according to the new SHA 2011 and a revision was done from 2009-2013. while the same methodology was sent the data for 2014-2015.

Transition table from SHA 1.0 to SHA 2011 codes

System of Health Accounts SHA 1.0	Funding Sectors (HF)	System of Health Accounts SHA 2011
HF.1.1	General Government (excl. Social Security Funds)	HF.1.1
HF.1.2	Social Security Funds (SSFs)	HF.1.2
HF.2.2	Private Voluntary Insurance Schemes	HF.2.1
HF.2.3	Private Households Out-of-pocket Expenditures	HF.3.1
HF.2.4	Non Profit Institutions Financing Schemes	HF.2.2
HF.2.5	Corporation Financing Schemes	HF.2.3
HF.3	Rest of the World	HF.4
HF.0	n.e.c	HF.0
System of Health Accounts SHA 1.0	Health care providers (HP)	System of Health Accounts SHA 2011
HP.1	Hospitals (public and private)	HP.1
HP.2	Residential. Long-term care facilities	HP.2
HP.3.1-3.4, HP.3.6	Providers of ambulatory health care	HP.3

APPENDIX

HP.3.5, HP.3.9	Providers of ancillary services	HP.4
HP.4	Retailers and other providers of medical goods	HP.5
HP.5	Providers of preventive care	HP.6
HP.6	Providers of health care system administration and financing	HP.7
HP.7	Rest of Economy	HP.8
HP.9	Rest of the World	HP.9
HP.0	n.e.c	HP.0

The SHA is organised around a tri-axial system for the recording of health expenditure, defining:

- ▶ health care by function (HC)
- ▶ health care service provider industries (HP) and
- ▶ health care financing agencies (HF)

More specifically, on the basis of the aforementioned system (SHA 2011), for each expenditure category the following items are depicted:

- ▶ The funding agency - e.g., the Ministries (HF 1.1.), Social Security Funds (HF1.2), Households (HF 3.1), etc.
- ▶ The health care provider to which this expenditure is directed- e.g., General Hospitals (HP 1.1), Offices of physicians (HP 3.1), Offices of dentists (HP 3.2), etc.
- ▶ The health care function pertaining to each expenditure- e.g., Inpatient curative care (HC 1.1), Outpatient curative care (HC 1.3), etc.

The SHA 2011 has been adopted by most of OECD countries since all Member States of the EU are obliged to implement this system (pursuant to Community legislation) in order to transmit economic data for health care (from 2003 onwards) to OECD, Eurostat and WHO, through a common questionnaire jointly developed by the above three Organizations.

The SHA (for Greece) was developed in line with the «bottom-up» approach and following the funding agencies perspective. Health expenditure data were transmitted by the relevant Ministries (the Ministry of Health and Social Solidarity, the Ministry of Finance, the Ministry of National Defense, the Ministry of Culture, Education & Religious Affairs, and the Ministry of Interior & Administrative Reconstruction), by the Social Security Funds (SSFs), by the Hellenic Association of Insurance Companies (EAEE), by Individual Non-Governmental Organizations, by the Church of Greece, by the Household Budget Survey (HBS) conducted by ELSTAT and the Managing Authority of the Ministry of Health.

Health expenditure, according to the new SHA methodology 2011 is comprised by the respective expenditure for:

▶ **Care Services. Rehabilitation**

- HC.1 Hospitals (public and private)
- HC.2 Residential, Long-term care facilities
- HC.3 Providers of ambulatory health care

▶ **Ancillary Health Care Services**

- HC.4 Providers of ancillary services (eg. clinical diagnostic imaging and laboratory services, patient transport and emergency rescue services)

▶ **Products Supply for Outpatient Patients**

- HC.5 Retailers and other providers of medical goods (pharmaceuticals, vision glasses, hearing aids, orthopedic belts and accessories)

▶ **Other Medical Products. Healthcare Management etc**

- HC.6 Preventive Care Services & Public Health
- HC.7 Healthcare Management & Social Security Funds
- HC.9 Non-specialized services by type

▶ **Funding of Health Expenditure:** is defined as the Funding on Consumption Expenditure of resident units on health care goods and services, irrespective of where that consumption takes place (i.e., in the economic territory of the country or abroad), and irrespective of the funding agency (which may be in the economic territory of the country or abroad). Therefore, imports of health care goods and services must be included, while exports must be excluded.

▶ **Public or Private Funding** of Expenditure is defined on the basis of the type (public or private) of the funding agency and on the basis of the type (public or private) of the Health Care Provider. For example, public funding of expenditure on hospitals does not mean the total expenditure of the public hospitals but the total amount of funding that both the public and the private hospitals get by the public funding agencies (Ministries, Social Security Funds).

▶ **Inpatient curative care services HC.1.1**

Under this category are included activities relating to inpatient services in either public, private, psychiatric and special treatment hospitals.

▶ **Day cases of curative care HC.1.2**

Under this category are classified all expenses relating to blood dialysis that are covered by any Social Security Fund (SSF).

▶ **Outpatient curative care HC.1.3**

This category reflects medical and paramedical examination for patients from outside the hospital. Moreover, services such as mobile care units, private clinics and diagnostic centers are also included under this category.

▶ **Pharmaceutical and other medical non-durables HC.5.1**

This category includes various pharmaceutical products such as medicines, sera, vaccines, bandages etc.

▶ **Therapeutic appliances and other medical durables HC.5.2**

This category includes medical supplies such as eyeglasses, hearing aids, orthopedic devices etc

7.2 PHARMACEUTICAL EXPENDITURE-SALES

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

EOF records sales of medicinal products from pharmaceutical companies to hospitals, wholesalers and pharmacies, on a monthly basis. On the other hand, according to the OECD’s International Classification of Health Accounts, with which Greek statistics have been harmonized, pharmaceutical spending is the total expenditure for medicinal products prescribed for outpatient care (non-hospital treatment). Therefore, **pharmaceutical expenditure is only a fraction of total pharmaceutical sales.**

More precisely, pharmaceutical sales are composed of:

- (a) Public pharmaceutical expenditure which is incurred by social insurance funds (partially returned to public funds, as VAT of 6% and mandatory discounts/ rebates/ clawback from pharmacists and pharmaceutical companies are included);
- (b) Hospital sales from pharmaceutical products (invoiced at hospital price = ex-factory price minus 8.74% - rebates);
- (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) Patient’s copayment, which does not burden social security funds.

Regarding point (b), it should be noted that pharmaceutical sales to hospitals are included in hospital expenditure, so should be excluded from the analysis to avoid double-counting.

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



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