THE PHARMACEUTICAL MARKET IN GREECE

FACTS AND FIGURES

2021

FOUNDATION FOR ECONOMIC & INDUSTRIAL RESEARCH

40 YEARS

SFEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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"THE PHARMACEUTICAL MARKET IN GREECE: FACTS & FIGURES 2021"

It is with great pleasure to preface the renewed annual edition 'The Pharmaceutical Market in Greece: Facts & Figures 2021', produced by research staff of IOBE in collaboration with SfEE.

This report intends to provide the most comprehensive overview of key facts and data of the pharmaceutical market in Greece, to inform both our members and other stakeholders in the broader health sector.

More specifically, this year's edition attempt to include all data available until the end of 2021, to present an updated profile of the pharmaceutical market and the main changes that occurred.

This year's edition takes place in the wake of the COVID 19 pandemic, an unprecedented crisis for the world, which underscored the definite importance of the discovery. development and access to new diagnostics, new treatments and vaccines to tackle global health threats, the sufficient financing of health systems, but also cooperation between the pharmaceutical industry and governments.

However, the COVID-19 crisis has also demonstrated the crucial importance of the productive capacity of Europe and our country. At the same time, it demonstrates the immediate need to create and sustain a political and economic environment that supports innovation and research and development

We would like to thank the IOBE and SfEE research staff.

Nikos Ragoussis

President of the Data Monitoring Committee

Olympios Papadimitriou

President of SfEE

EXECUTIVE SUMMARY

The effects of the pandemic in Europe and the whole world from 2020 and 2021 continuing until today. Europe implemented policies to address health problem and to combat the economic effects of the pandemic, with extensive fiscal and monetary measures. In the first phase, the temporary SURE program (temporary Support to mitigate Unemployment Risks in an Emergency - SURE) activated, to preserve employment in the member states, while another important measure was the activation of the general escape clause, which gave financial capacity to the member states to deal with the pandemic. In addition, the Recovery Fund (Next Generation European Union - NGEU) has gradually started to be activated, and the new Programming Period 2021-2027, i.e. the New ESPA. In addition to the fiscal tools that have been implemented or are expected to be implemented, the European Central Bank (ECB) is supporting the eurozone economy with liquidity enhancement measures. From the middle of 2021 and especially towards the end of the year, a parallel crisis is also taking place, this time in the energy sector, with a sharp escalation of prices, pushing inflation to historically high levels in Europe and Greece.

The needs of the population for health care are affected by the **demographic trends:** high life expectancy in Greece (81.2 years, higher than EU27 average 81.0 years in 2020), negative natural change (births - deaths) decreased by 46,000 people (2020), leads to steady **reduction of the population**-and increased **ageing population** (over 65 years) from 22.9% of the total population in 2022 rising to 33.5% in 2060 signaling increased pressure on the health and social security systems. Over time, there has been a strong rise in the number of deaths in Greece due to circulatory system diseases in 2019 accounted for 35.4% of total deaths, while the number of deaths due to neoplasms estimated at 24.2% of total deaths.

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.

Total health expenditure decreased by -25.9% during the period 2010-2020 (+5.8% in Southern countries, +20.7% in the EU), amounted at €15.7 bil. in 2020 (9.5% of GDP). **Public health expenditure** decreased by -32.9% (+3.1% in Southern countries, +24.6% in the EU) over the same period, amounted at €9.7 bil. in 2020 (5.9 % of GDP). The decline in public health expenditure has resulted in a shift in health spending to the private sector, with private health expenditure reaching 38.2% in 2020 (25.9% in Southern countries, 18.8% in the EU).

With regards to the pharmaceutical expenditure, **total outpatient pharmaceutical expenditure** in Greece estimated at €4.0 bil. in 2021, (€2,0 bil. is public pharmaceutical expenditure). The significant reduction in the public sector's contribution to pharmaceutical spending has resulted in a shift to the private sector where for 2021 patient participation in outpatient pharmaceutical expenditure reaches around €650 mil. and industry in €1.3 bil.

Public outpatient pharmaceutical expenditure decreased by -60.8% over the period 2009-2021, while **public hospital pharmaceutical expenditure** amounted to €621 mil. in 2021 decreased by -18.7% in comparison to 2015 (€764 mil.) before the introduction of closed budget. The continuous reduction in public hospital pharmaceutical expenditure resulted in the increase of industry's contribution, through flat mandatory returns and discounts (rebate and clawback) €624mil in 2021.

As a result, the industry for 2021 with rebate and clawback mechanisms has reached the needs of Greek patients for pharmaceutical coverage with **1 out of 2 medicines (50%).**

Despite the significant impact of fiscal adjustment on public funding, the pharmaceutical industry remains a pillar for investment in Greece with Research and Development (R&D) expenditure close to 7% of total R&D expenditure in Greece (2019) and 3,499 clinical studies independent of phase and stage conducted the period 2002-2021 (2,000 completed). Production of pharmaceutical products in Greece was estimated at €1.7 bil., with Gross Value Added (ex-factory) at €1.4 bil. (6.9% of total manufacturing). Employment in the manufacturing of pharmaceutical products in Greece was estimated at 25.1 thousand people in 2021, with 49.5% of them with university education, compared to 37.5% of the total economy and 23.3% of the total manufacturing. In 2020, sales of pharmaceutical products in pharmacies & wholesalers (in value) amounted to €4.6 bil., increased by 3.7% compared to 2019, while sales to hospitals and EOPYY pharmacies amounted to €2.4 bil. Increased by 5.0%

Lastly, imports and exports of pharmaceutical products amounted to €4.5 bil. and €2.9 bil., respectively in 2021 indicating a decline compared to 2020. Exports of pharmaceutical products accounted for 7.3% of total Greek exports in 2021.

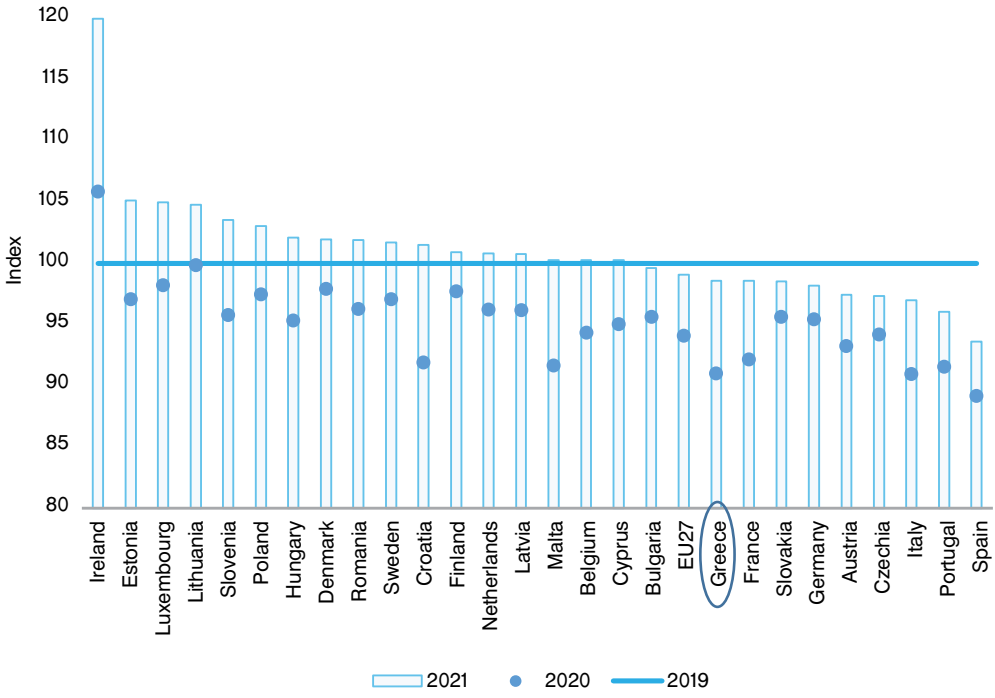
ECONOMIC ENVIRONMENT

The planet was tested by the pandemic, with the effects in Europe continuing in 2021. Europe implemented policies to address health problem and to combat the economic effects of the pandemic, with extensive fiscal and monetary measures. In the first phase, the temporary SURE program (temporary Support to mitigate Unemployment Risks in an Emergency - SURE) activated, to preserve employment in the member states, while another important measure was the activation of the general escape clause, which gave financial capacity to the member states to deal with the pandemic. In addition, the Recovery Fund (Next Generation European Union - NGEU) has gradually started to be activated, and the new Programming Period 2021-2027, i.e. the New ESPA. In addition to the fiscal tools that have been implemented or are expected to be implemented, the European Central Bank (ECB) is supporting the eurozone economy with liquidity enhancement measures. From the middle of 2021 and especially towards the end of the year, a parallel crisis is also taking place, this time in the energy sector, with a sharp escalation of prices, pushing inflation to historically high levels in Europe and Greece.

1.1 MACROECONOMIC ENVIRONMENT

Based on GDP data, almost all countries experienced a small or large drop of income in 2020, among them Greece, with the exception of Ireland which showed a positive growth rate of GDP in 2020. Apart from Greece, Spain and Italy had a strong contraction of GDP by around 10% compared to 2019. On the other hand, apart from Ireland, strong resilience in 2020 was recorded by Lithuania, Luxembourg and Denmark, with GDP declining only slightly, while the European Union recorded an average recession term by -5.9% in 2020. The measures of the European Commission and the European Central Bank and the interventions of the Member States strengthened all EU economies in 2021 compared to 2020. Some countries have returned near to 2019 levels, such as Ireland which has even surpassed them, Lithuania and Luxembourg, while others are still far behind such as Spain, Portugal and Italy. The countries with the biggest recovery in 2021 compared to 2020 are Ireland, Croatia, Malta and Estonia.

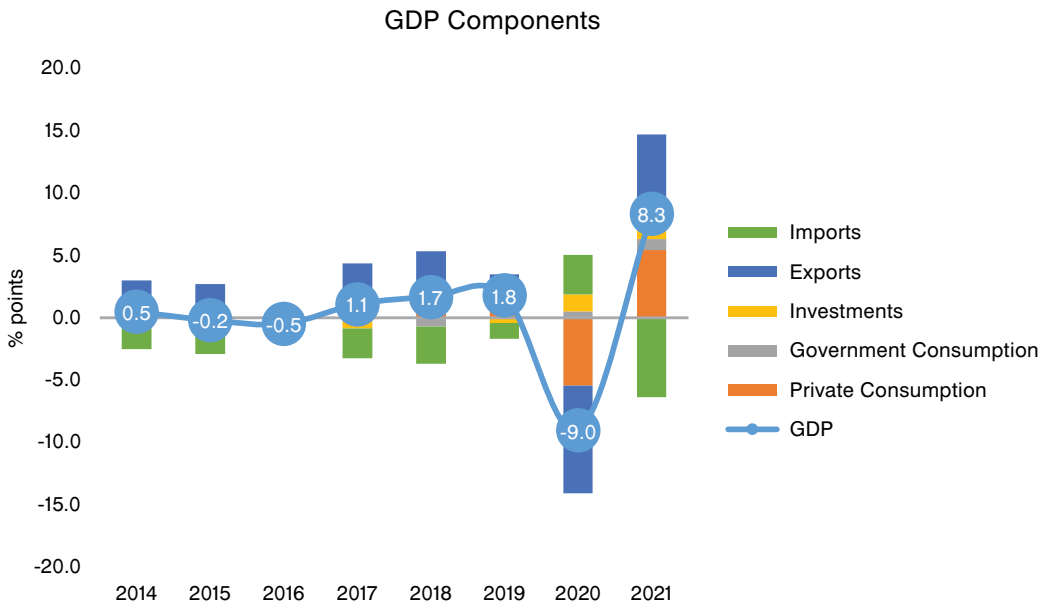
Figure 1: Performance indicator* GDP based on 2019



SOURCE: Eurostat 2022, data processing IOBE, *Ratio of 2020 and 2021 GDP compared to 2019 levels, where 2019 GDP takes the value 100.

Due to the pandemic GDP in Greece contracted by 9% in 2020. This decrease was driven by the drop in exports, with a decrease of 8.6 points and in private consumption (-5.4 points), while the decrease in imports offset the overall fall. In 2021, the GDP increased by 8.3%, very close to 2019 levels (at 98.6%), with the strengthening of exports and private consumption the main drivers.

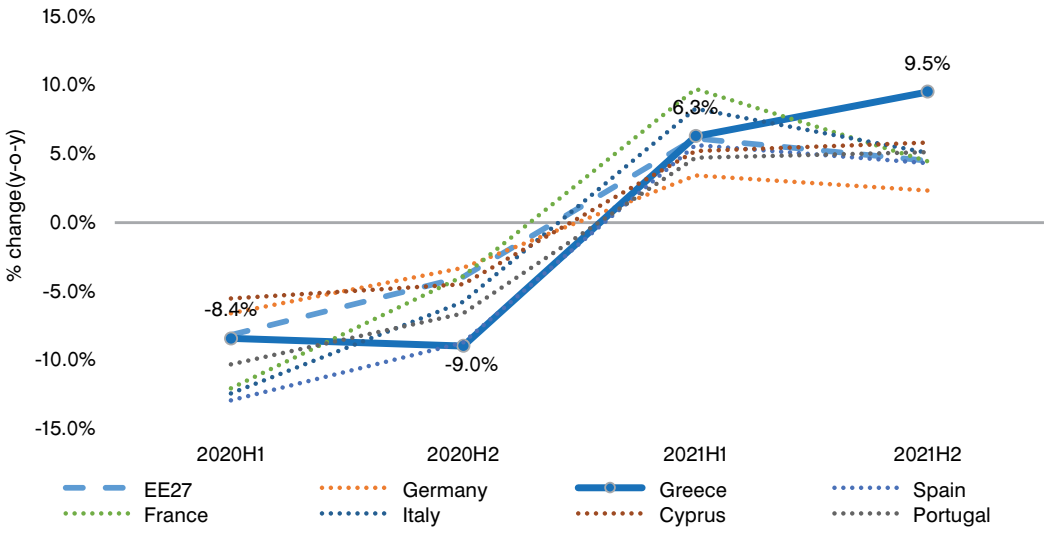
Figure 2: GDP components (€) and annual change (%) – Greece



SOURCE: Eurostat 2022, data processing IOBE

Based on the data available, GDP shrank roughly the same intensity in both the first and second semester of 2020, while the shrank in the second quarter of the year was stronger for Greece compared to other member states. The 2021 recovery in the first half of the year was of moderate intensity as other countries grew faster, while Greece showed significant GDP growth in the second half of +9.5%, compared to 4.5% in the EU27 average and much higher than other European countries, largely fueled by the increase in tourist receipts.

Figure 3: GDP development by country (by semester)

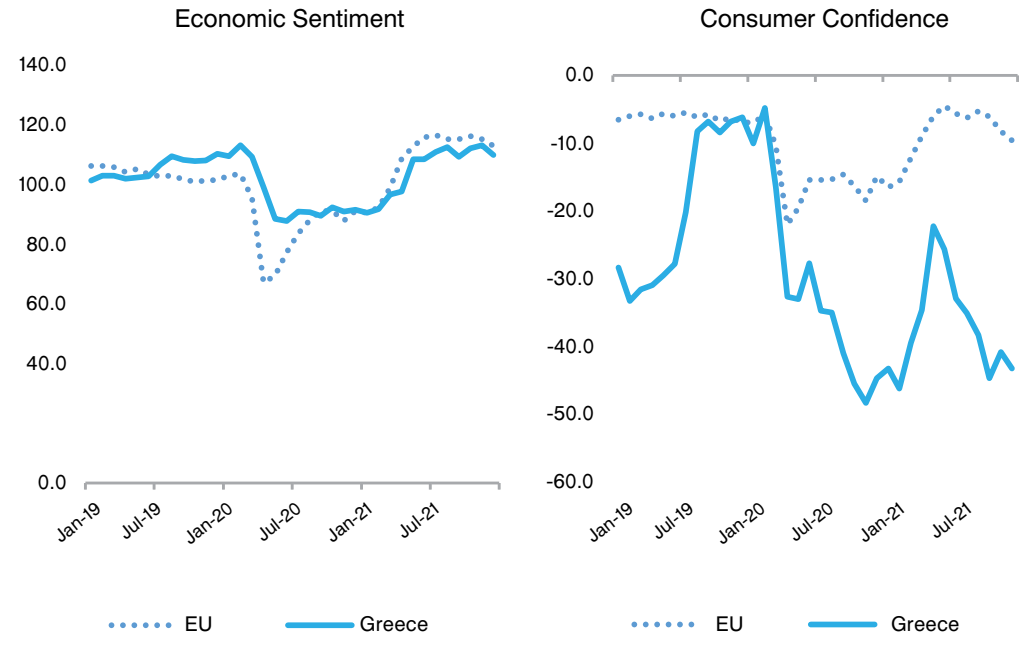


SOURCE: Eurostat, data processing IOBE

Economic sentiment index in Greece remained at high levels throughout the 2020, compared to EU. Economic sentiment index counts business climate in Industry, Trade, Services and Construction but also the consumer confidence as well. Index contracted in Greece from January of 2020 to June by 23.2 points. The fall of the index was larger in EU, while it started from lower point at the beginning of the year (2020). In contrast to the economic sentiment, consumer confidence in Greece contracted further during the year. In EU consumer confidence halted, after the fall of the first four months.

In 2021 economic sentiment index increased in Greece, and also in EU, while consumer confidence continued to fall after the improvement of the first five months, maybe due to inflation increasing since August. Therefore, GDP improvement in the second quarter of 2021, following the tourist receipts, combined with the business climate upturn, despite the consumer confidence fall.

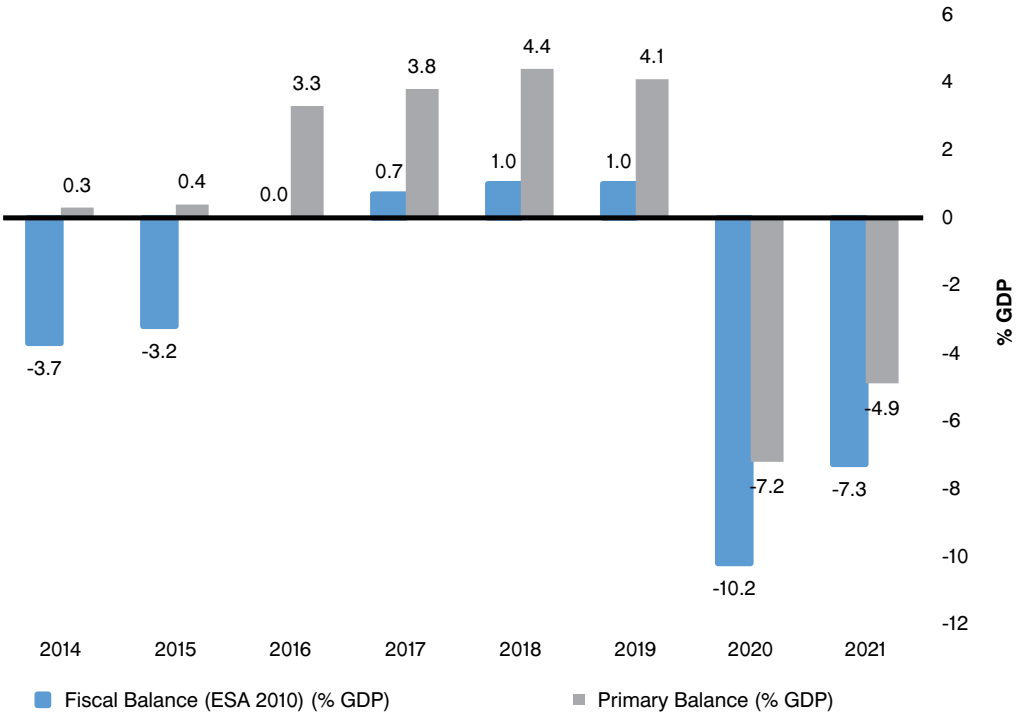
Figure 4. Economic Sentiment & Consumer Confidence



SOURCE: European Commission, DG ECFIN

The need for measures supporting the economy, by expanding government spending and shrinking taxation - assisted by the general escape clause- led to sizeable fiscal deficits. Fiscal deficit stood at -10.2% of GDP in 2020, while in 2021 the deficit ratio contracted due to the expansion of nominal GDP. Primary deficit estimated at -7.2% of GDP in 2020 and -4.9% in 2021. It's noted that before COVID-19 the Greek economy should be able to achieve primary surpluses up to 3.5% of GDP until 2022.

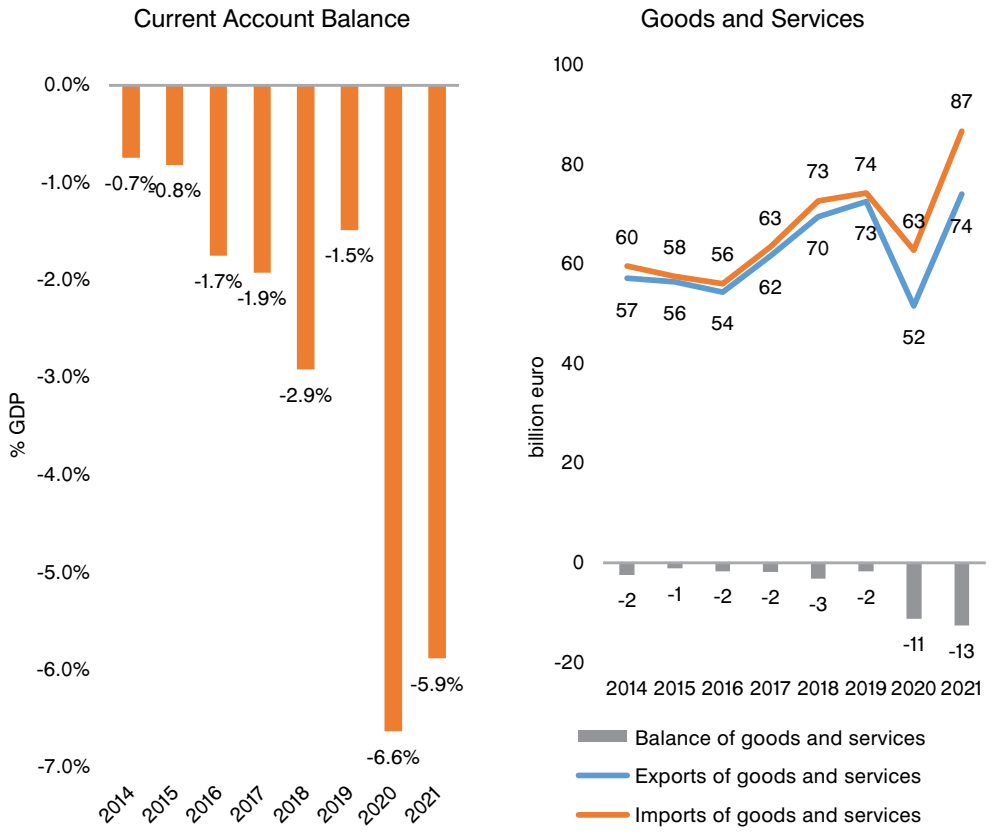
Figure 5: Fiscal Balance



SOURCE: ELSTAT, 2022, AMECO 2022, data processing IOBE. The Fiscal Balance is defined as the balance of income and expenditure of government. It includes interest on debt repayment but does not include the impact of the support to the financial institutions from all interventions during the financial crisis on the general government deficit. The primary balance is the fiscal balance excluding net interest payments on public debt.

In the external sector of the Greek economy, the Current Account Deficit rapidly increased in 2020-2021, compared to the previous period. Current Account Deficit was 5.9% (% of GDP) in 2021, with a small improvement by 2020, but it remains three times compared to the period 2014-2019. Goods and Services deficit, the largest component of the Current Account Balance, was €11-13 bil. in 2020 and 2021. Exports of Goods and Services contracted in 2020 by €21 bil. while imports fell by €11 bil. In 2021, the economic recovery in combination with higher prices at the second half of the year, led to an increase of the imports and exports at €87 bil. and €74 bil. respectively.

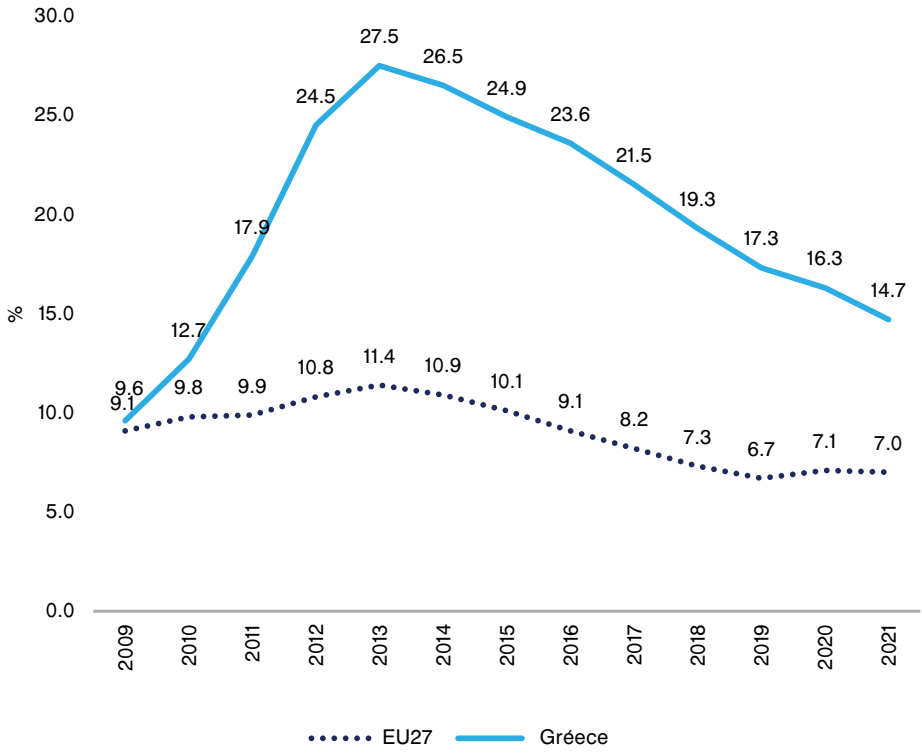
Figure 6: Current Account Balance



SOURCE: Bank of Greece, 2022, ELSTAT, 2022, data processing IOBE. 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).

Unemployment rate is gradually decreasing since 2013, reaching 16.3% in 2020, despite the adverse effects of the pandemic on economy. The economic measures halted the negative effects of the pandemic and a percentage of the active population transformed to inactive due to lockdowns, leading to unemployment rate fall. In 2021 unemployment rate continued to fall to 14.7%, especially forced by the tourist industry recovery at the third quarter.

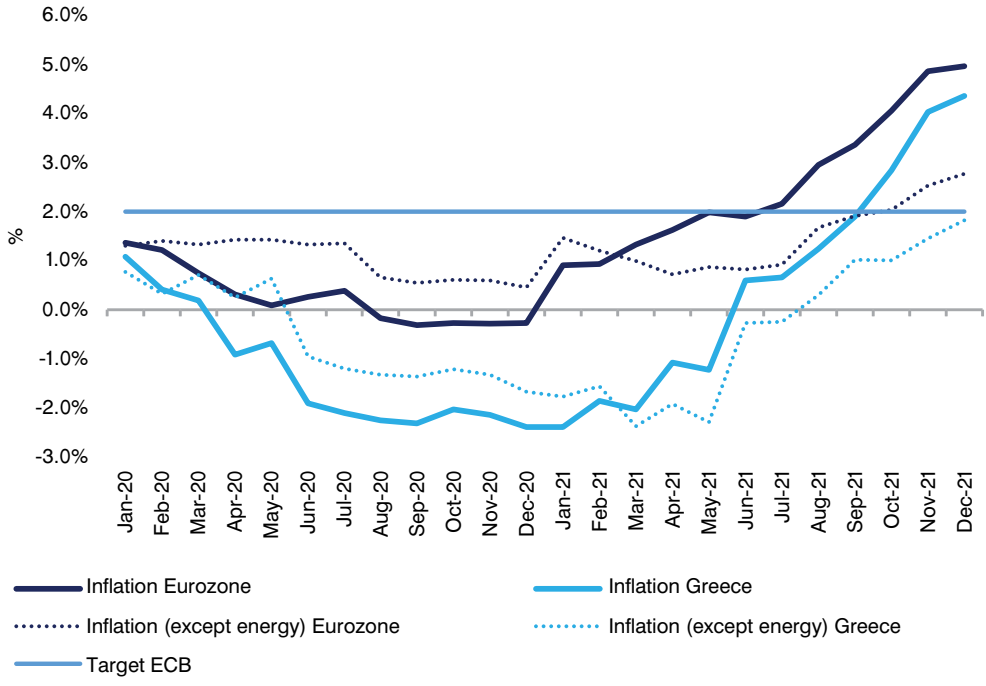
Figure 7: Unemployment rate Greece-EU27



SOURCE: Eurostat, 2022, data processing IOBE

Inflation had significantly decreased during the last 20 years, but it started to increase again by the end of 2020. Global supply chains disturbances due to the pandemic, with raw material shortages, transportation issues etc., but also fiscal and monetary expansions increased prices. Additionally, to these issues, geopolitical problems increased energy cost pushing the prices furthermore. Harmonized Consumer Index Price (HCIP) in Greece escalated to 4.4% in December 2021, compared to deflation -2.4% in December of 2020. The same happened in Eurozone, while form July of 2021 for Eurozone and from September for Greece, inflation exceed the 2% target in the medium term. A large part of the inflation is due to energy cost, while the core inflation is much lower in Greece and Eurozone.

Figure 8: Inflation Greece-EA

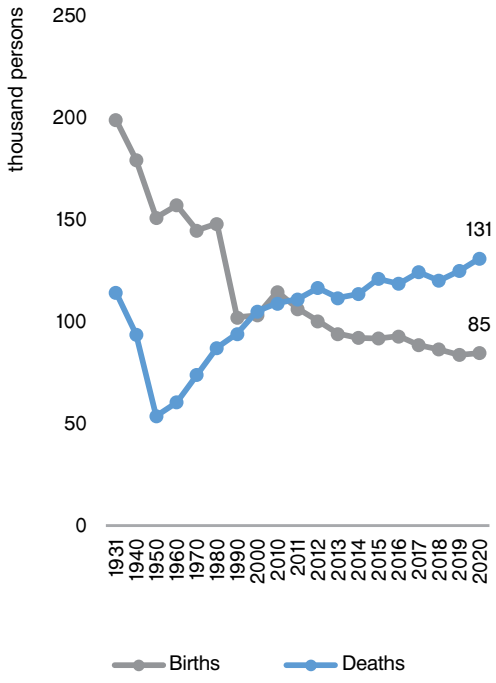


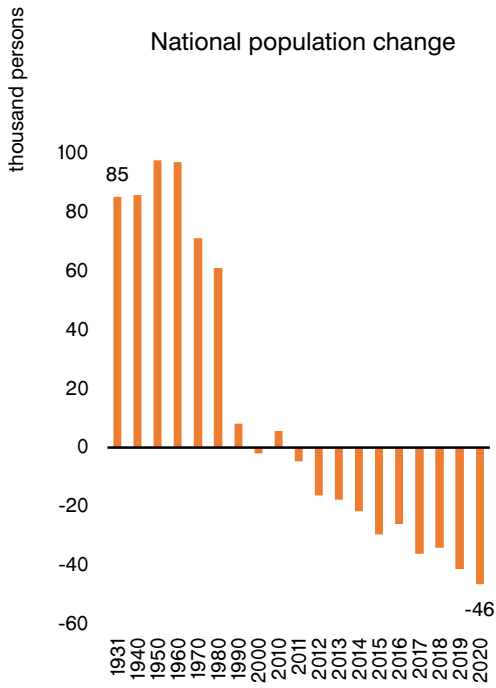
SOURCE: Eurostat, 2022, data processing IOBE.

2.1 NATURAL POPULATION CHANGE

The number of live births in Greece amounted to 84.8 thousand in 2020 recording an increase of 1.2% in comparison to previous year, after a three-year decline, while compared to 10 years ago, births are decreased by 30%. The number of deaths recorded an increase of 4.9%, amounting to 131 thousand at the highest recorded level historically. As such, the natural population change (difference births - deaths) result in an overall reduction of -46 thousand persons in 2020.

Figure 9: Natural population change (thousand persons)-Greece

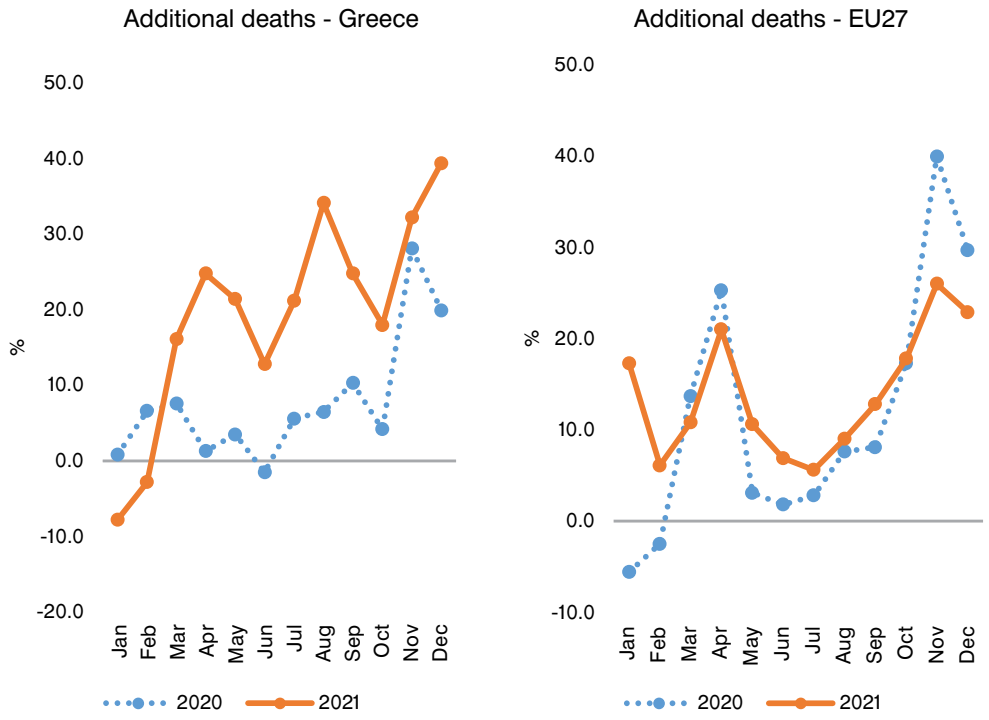




SOURCE: ELSTAT., 2022 *Natural population change (natural balance) is defined as the difference between births and deaths without taking into account net migration (immigrants – emigrants) ** The number of births does not include stillbirths, which in 2020 amounted to 440

Additional deaths per month recorded in each country compared to previous years' values due to the pandemic. Greece in 2020 showed a sluggish increase in additional deaths, with an increase only in the last months of the year, while on the contrary, in 2021 recorded an increasing trend of additional deaths. In the EU27 additional deaths peak in April and November 2020 and 2021.

Figure 10: Additional deaths due to COVID-19

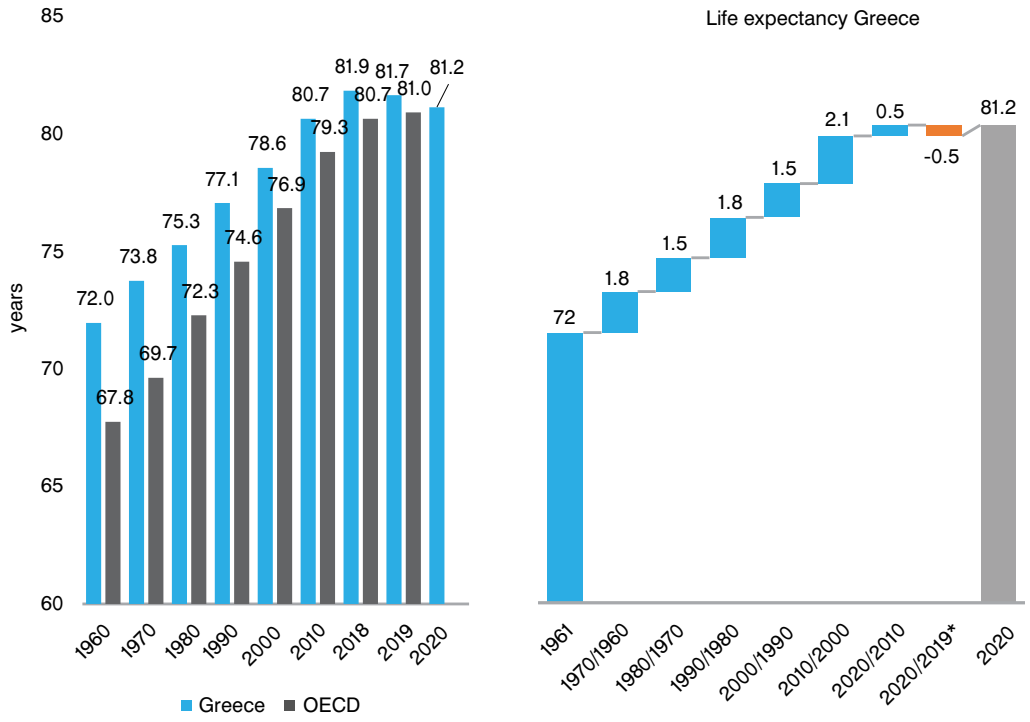


SOURCE: Eurostat, 2022, Additional deaths: The difference in total deaths from all causes per month compared to previous years' values

2.2 LIFE EXPECTANCY

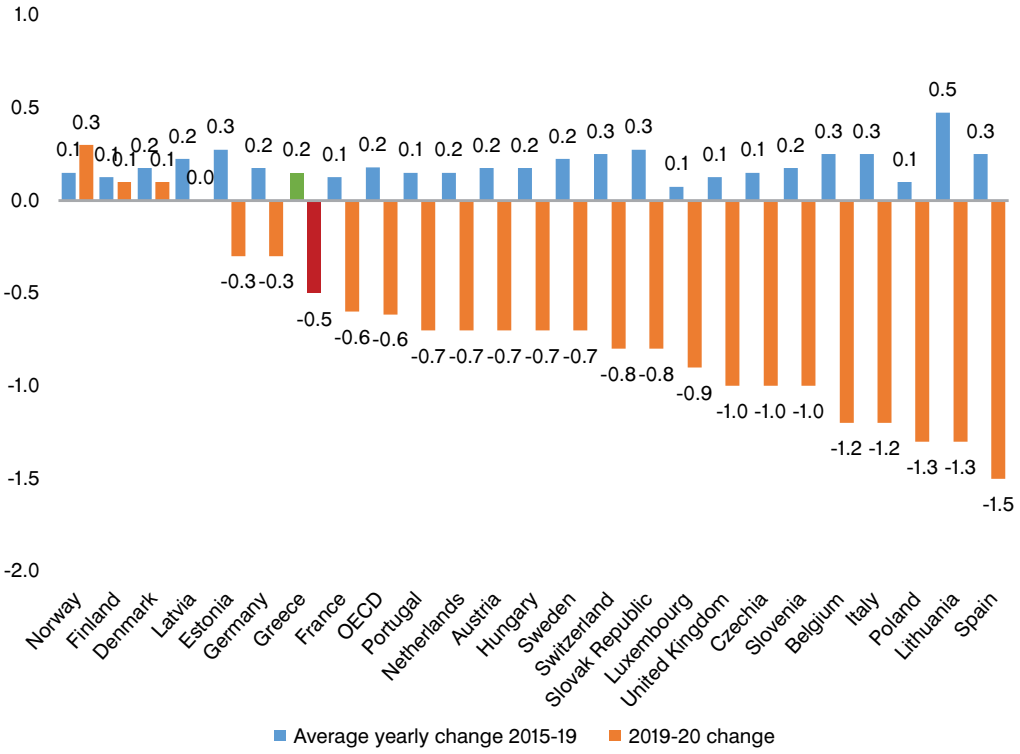
The technological advances, improvement in the provision of healthcare services, contribution of R&D and introduction of innovative new drugs and therapies partially are some of the most important factors explaining the increase of life expectancy. Life expectancy in Greece has increased considerably by 9.2 years during 1960-2020 despite the decline from 2018 and it is higher than the average of OECD countries in the same period. Every decade life expectancy in Greece extended by 1.5-2.0 years, while a negative change was recorded in 2020, with Greeks "losing" 6 months.

Figure 11: Evolution of life expectancy at birth (years) in Greece-OECD



SOURCE: OECD, Health Statistics 2022

Figure 12: Reductions in life expectancy during the pandemic

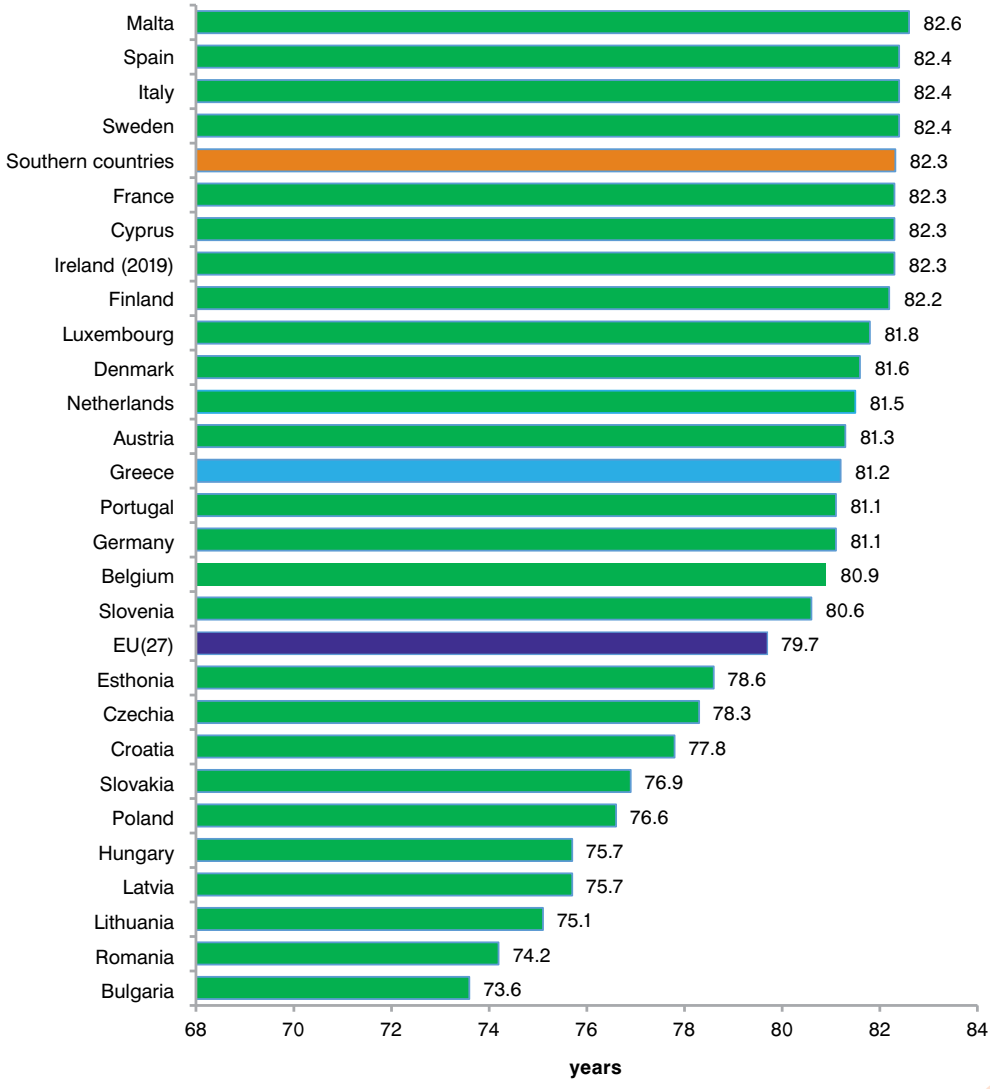


SOURCE: OECD Health Statistics 2021; Arias, Tejada-Vera and Ahmad, 2021

2.3 AGEING POPULATION

Life expectancy in Greece reached 81.2 years in 2020, which is higher from EU27 average (79.7 years) and lower than in Southern countries (82.3 years). The highest life expectancy was recorded in Malta, Spain and Italy.

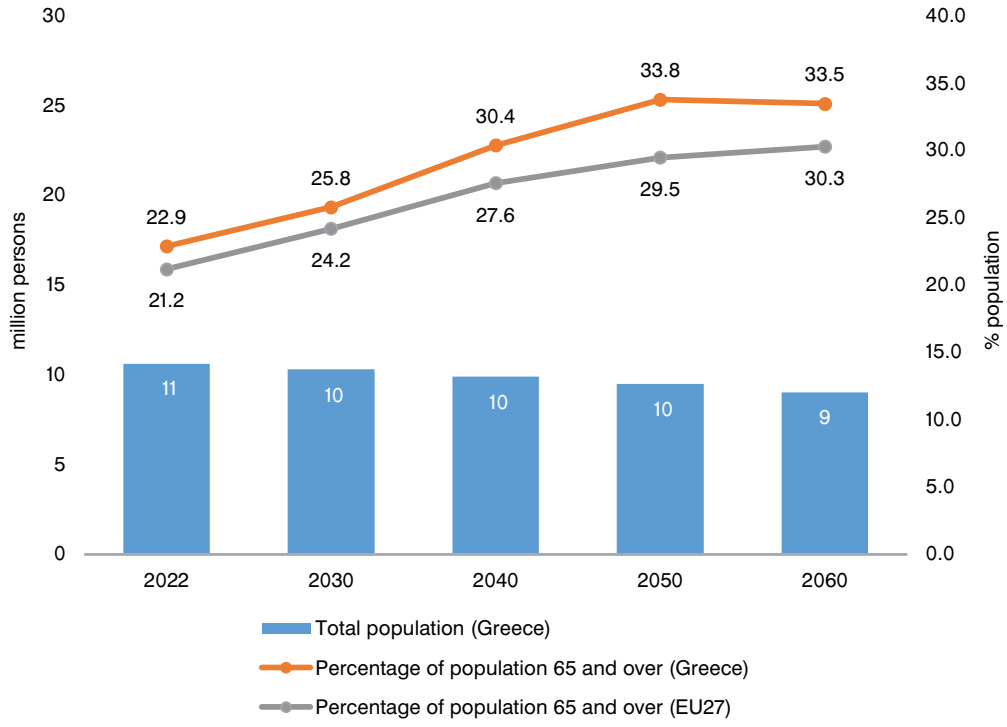
Figure 13: Life expectancy at birth (years) Greece-EU27-Southern countries (2020)



SOURCE: OECD, Statistics 2022, Eurostat 2022, data processing IOBE *Southern countries (Italy, Spain, Portugal).

Based on the latest revision from Eurostat, the steady decline of the population is expected to continue until 2060 (-15.5% in comparison to latest data). The percentage of people aged 65 and above in Greece is expected to increase from 22.9% of the total population in 2022 (21.2% in EU27) to 33.5% in 2060.

Figure 14: Population aged 65 and above (% total population) Greece-EU27



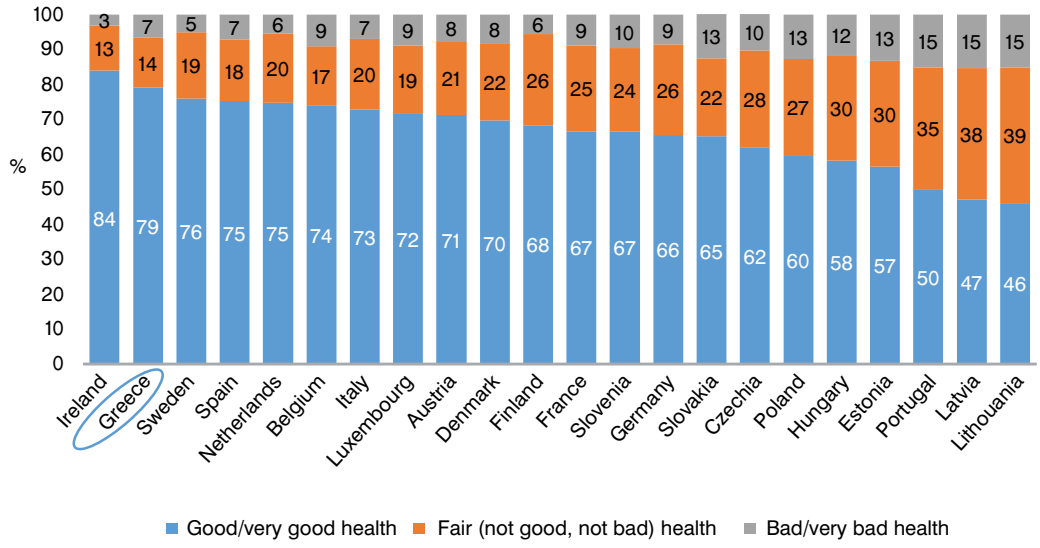
SOURCE: Eurostat, Population Projections, 2022, data processing IOBE *Not included the possible legalization of migration from 2015 onwards

2.4 DEPENDENCY RATIO-AGEING-PERCEIVED HEALTH STATUS

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. In 2020, Greece's dependency ratio reaches 56%, meaning that for every 2 active people there is 1 inactive, close to EU28 average (55%) and close to the average of Southern countries (55%). According to the United Nations, the dependency ratio in Greece is estimated to reach 92% by 2050.

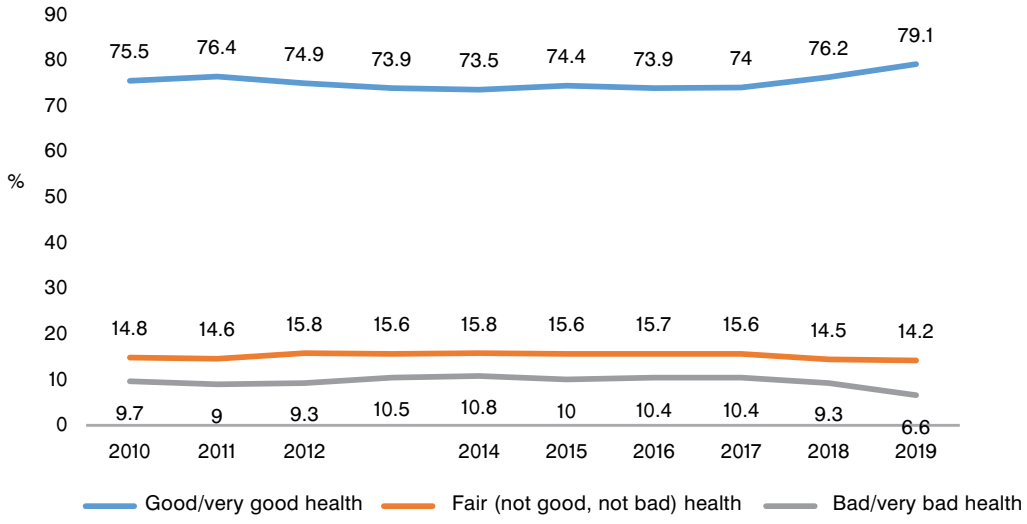
Self-reported health reflects people's overall perception of their own health, including both physical and psychological dimensions. For 2019, 79% of Greeks declared their perceived health status as very good and good, ranking second among EU countries after Ireland (84%).

Figure 15: Perceived health status, 2019



SOURCE: OECD Health Statistics, 2022

Figure 16: Perceived health status, Greece 2010-2019

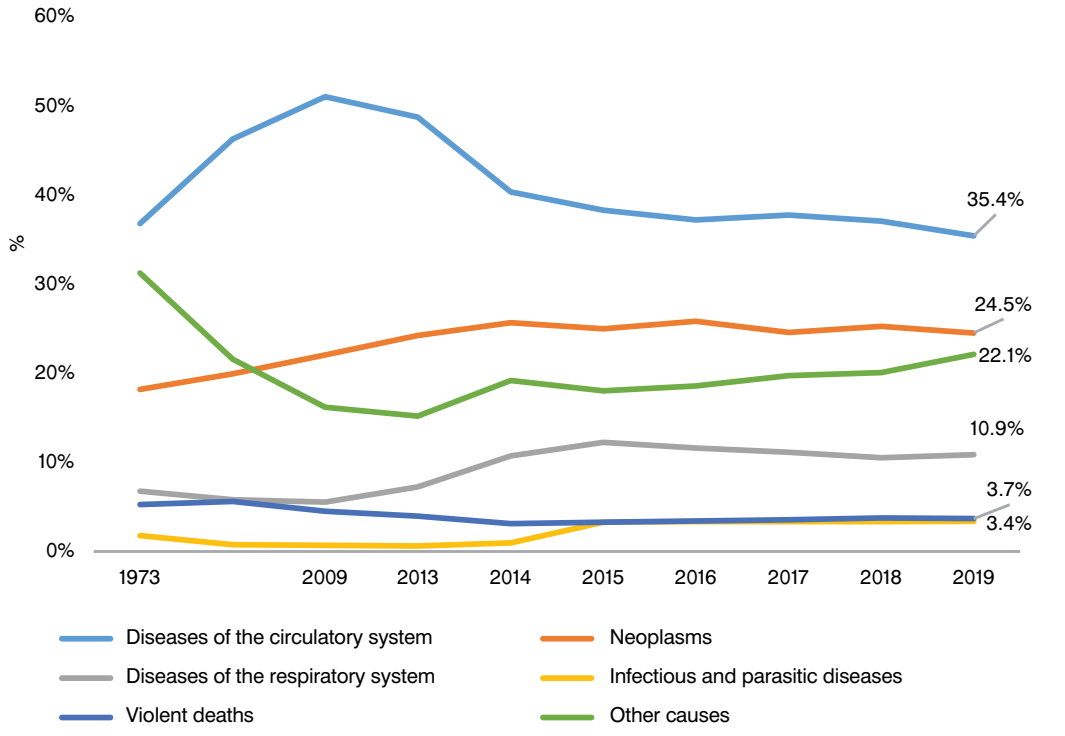


SOURCE: OECD Health Statistics, 2022

2.5 CAUSES OF DEATH-CHRONIC DISEASES-PREVENTION

Over time, a significant increase in the deaths due to circulatory system diseases is recorded, responsible for 35.4% of total deaths, despite the decline in recent years, while increase in neoplasms is recorded, accounting for 24.5% 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.

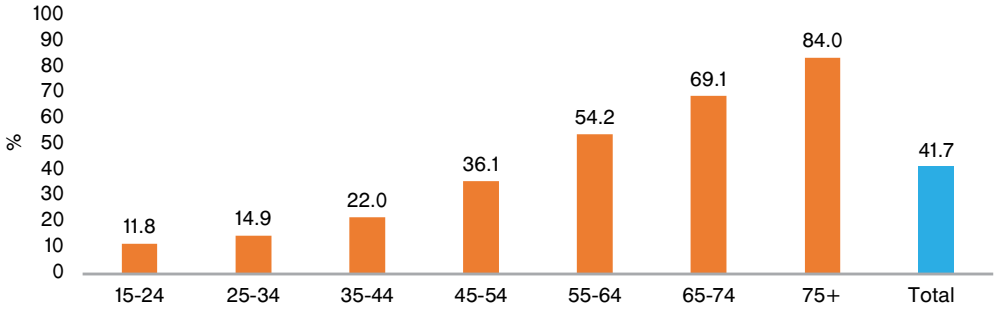
Figure 17: Causes of death (% of total deaths) – Greece (2019)



SOURCE: ELSTAT, 2022 data processing IOBE *Pursuant to the 10th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the subcategory "other external causes" of "violent deaths" includes the following: deaths due to misadventures to patients during surgical and medical care, deaths in cases where 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 while attempting to enforce the law and 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, nutrional deficiencies and immune disorders

According to ELSTAT, 4 out of 10 (41.7%) persons of the population aged 15 and over report suffering from a chronic illness or health problem. A chronic illness or health problem is reported by 5 out of 10 women (46.7%) and 4 out of 10 men (36.3%).

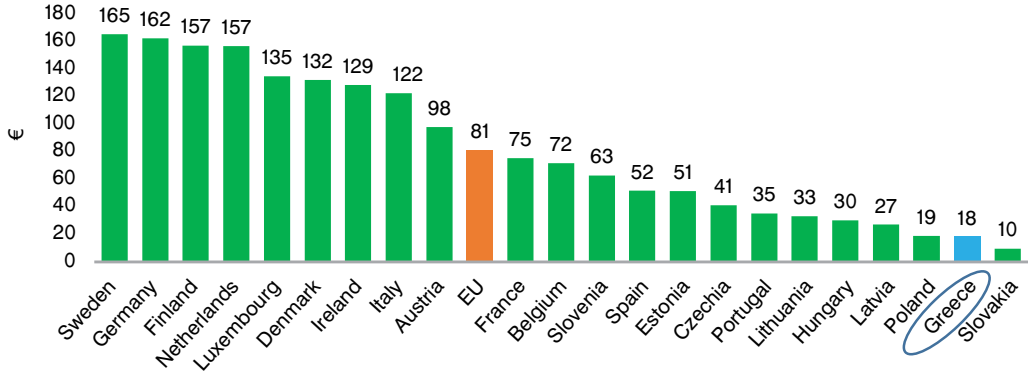
Figure 18: Percentage of population suffering from chronic health problem or chronic disease, 2019



SOURCE: ELSTAT, 2020, Chronic illness or health problem mean illnesses or health problems which have lasted, or are expected to last, for 6 months or more, with or without medication

In 2019 the per capita spending on prevention in Greece reached €18 (from €25 in 2009 and €17 in 2018), one of the lowest shares in EU23.

Figure 19: Prevention expenditure per capita, Greece-EU (2019)

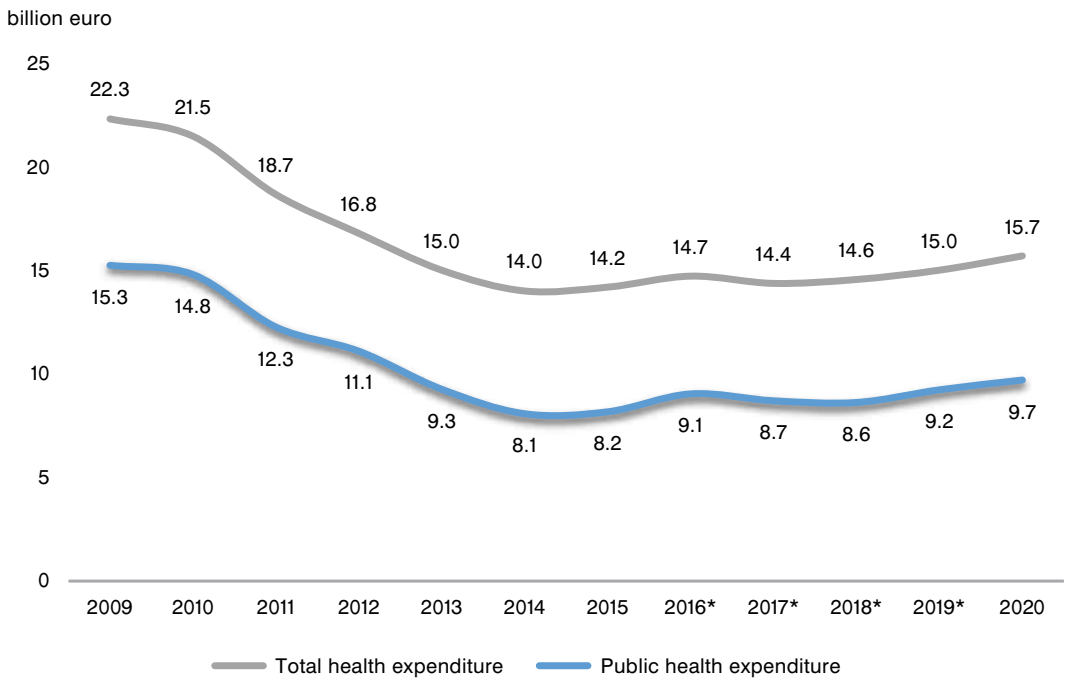


SOURCE: OECD, Health Statistics 2022

3.1 FUNDING ON HEALTH EXPENDITURE

In 2020, total health expenditure in Greece amounted to €15.7 bil., increased compared to 2019, also due to the needs by the pandemic. Public health expenditure reached €8.7 bil. increased by €474 million. compared to 2019 while private health expenditure increased by €215 million, to €6.0 billion. in 2020.

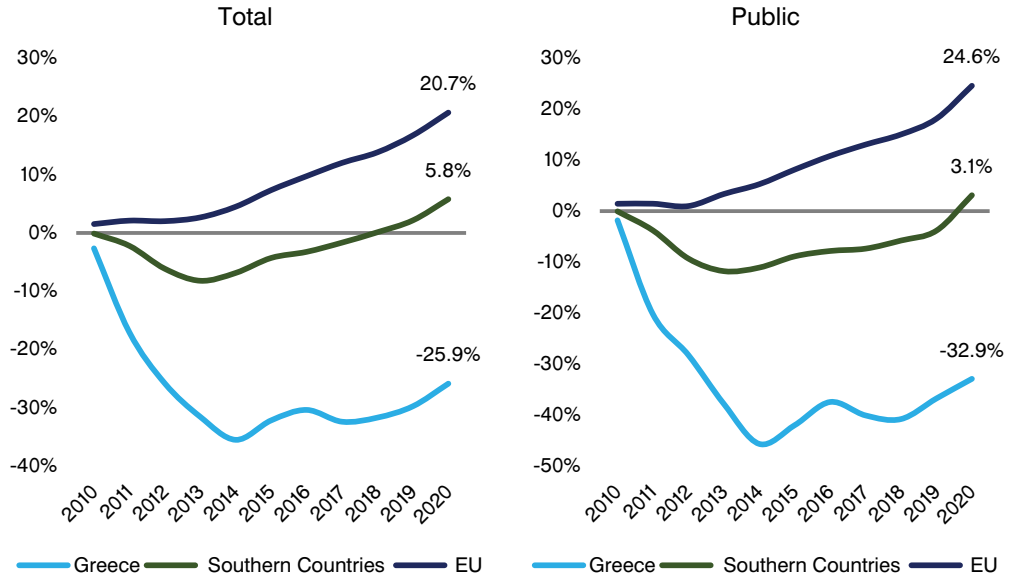
Figure 20: Total and public health expenditure (bil.€)



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT, 2022, data processing IOBE*. *Revised data. For the years 2015 and 2016 data for Social Security Funds (SSFs) (HF.1.2) in HC.1.1 and HC.5.1 categories have been revised due to primary data changes.

The period before the pandemic characterized by a decrease of health expenditure in Greece, in contrast to the EU and the Southern countries. Specifically, the index of GDP cumulative change in total health expenditure showed an increase of 2.1% in Southern countries, while an increase of +16.2% was recorded in EU and a decrease of -32.9% in Greece during the same period. Similarly, a cumulative decline of -3.7% was recorded in public health expenditure in Southern countries, while an increase of +17.9% was noted for EU. In Greece a decrease -42.5% during the same period.

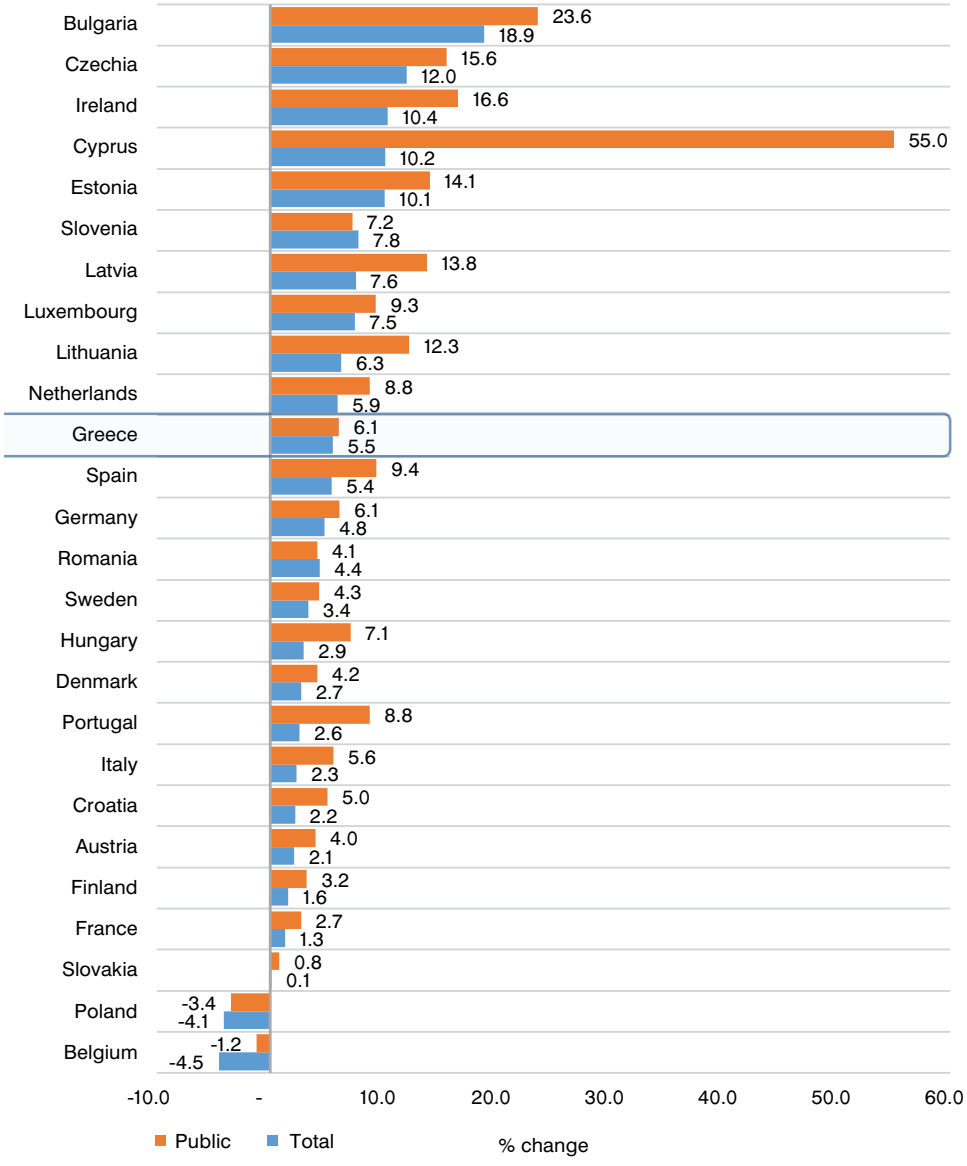
Figure 21: Index of cumulative change on health expenditure (%) Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, OECD Health Statistics, 2022, IOBE data processing Southern countries (Italy, Spain, Portugal). Percentage changes between 2010 and 2020 have been calculated in €2015 constant prices, OECD. EU except Malta.

The pandemic changed health policies in 2020, as it was imperative to strengthen health systems to address health challenges. In 2020 public expenditure increased in almost all countries.

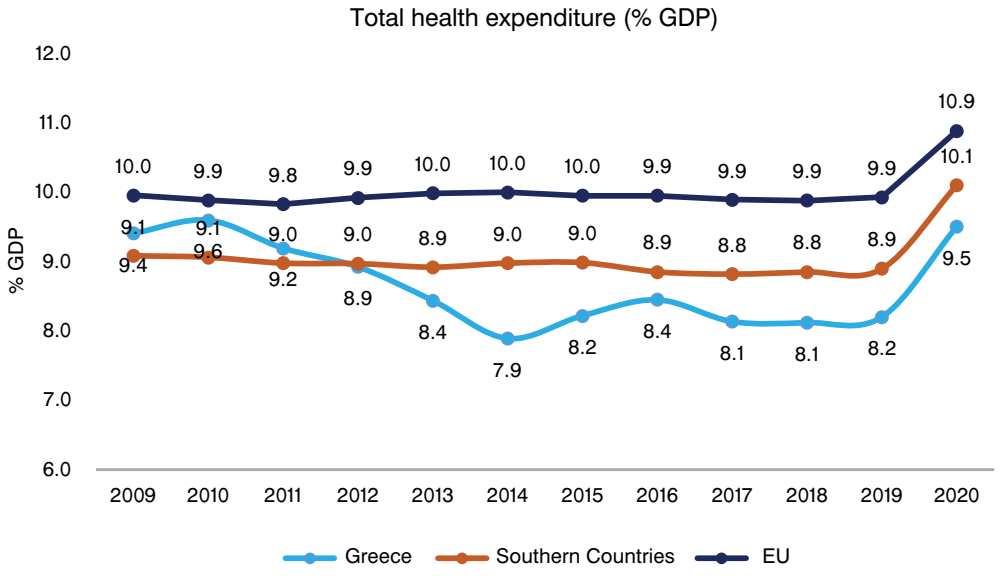
Figure 22: Health expenditure by country (% change 2020 vs 2019)



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT., 2020, OECD Health Statistics, 2022, data processing IOBE. Financing data in constant prices (€ 2015, OECD).

In 2020, recorded an increase in total health expenditure in terms of GDP, both in the EU and in Greece. At the same time with the increased health needs, a decrease in GDP was recorded, due to the limitation of economic activity. The total health expenditure in Greece corresponds to 9.5% of GDP, compared to 8.2% in 2019, while in EU increased to 10.9%, compared to 9.9%. In Greece, health expenditure declined in the period 2011-2019, close to 8.0%, compared to 9.1% in 2009. It is noted that even without the reduction in GDP, the share of expenditure would have increased in 2020 due to enhanced expenditure. In Greece with constant GDP, the share would be 8.6%, in the EU at 10.6% and in Southern countries at 9.0%.

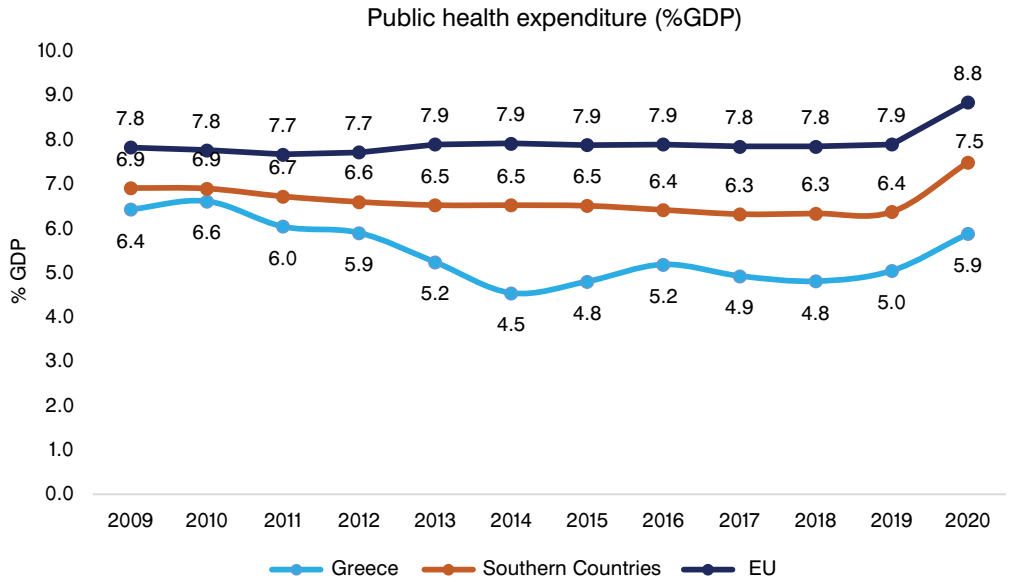
Figure 23: Total health expenditure (% GDP) Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT., 2022, OECD Health Statistics, 2022, data processing IOBE. Southern countries (Italy, Spain, Portugal).

Public health expenditure as a percentage of GDP in Greece amounted to 5.9% in 2020 compared to 5.0% in 20019. but remaining lower than the level of Southern countries, where the corresponding share was 7.5% and of EU at 8.8%. Despite the increase of financing in Greece, the percentage in terms of GDP remains lower throughout the reviewed period.

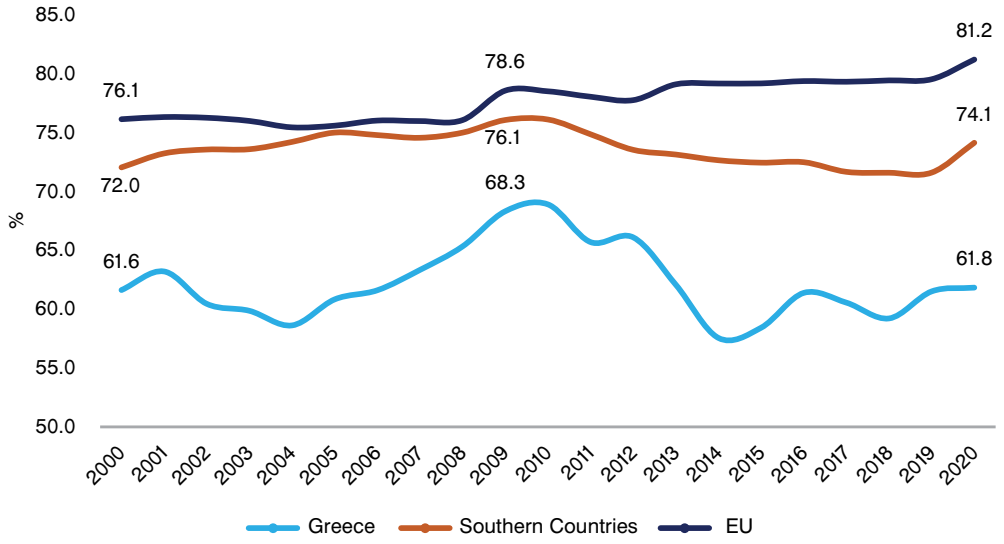
Figure 24: Public health expenditure (% GDP) Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT., 2022, OECD Health Statistics, 2022, data processing IOBE. Southern countries (Italy, Spain, Portugal).

Public health expenditure accounts for 61.8% of total funding for expenditure health in 2020, slightly increased compared to 68.3% in 2009, remaining below the EU average and Southern countries. It is noted that the share of public expenditure in Southern countries and EU increased by 2.5 and 1.0 units respectively in 2020.

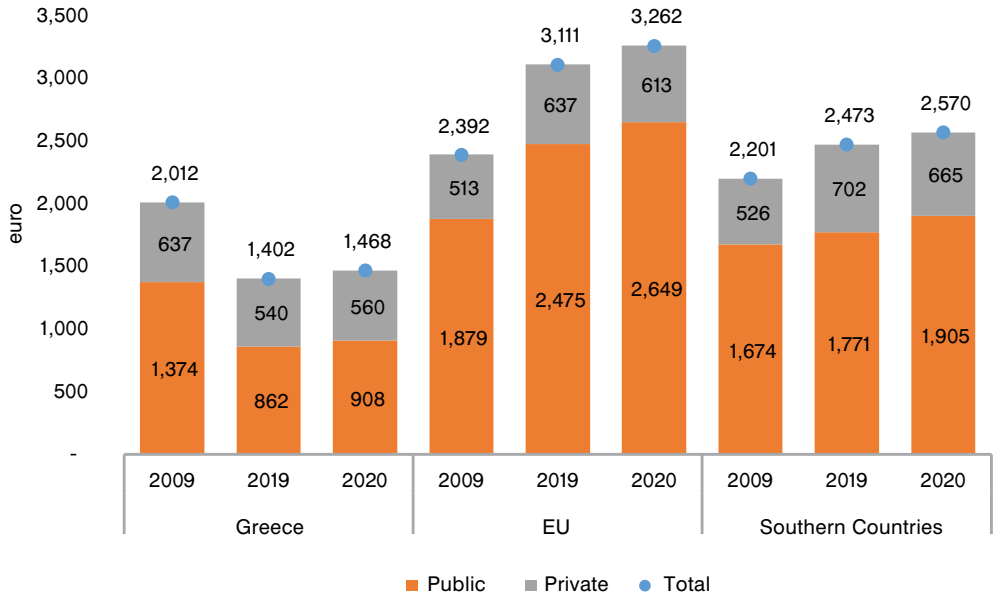
Figure 25: Public health expenditure (% of total expenditure) Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT, 2022, OECD Health Statistics, 2022, data processing IOBE. Southern countries (Italy, Spain, Portugal).

Total health expenditure per capita in Greece amounted to €1,468 in 2020 slightly increased compared to 2019 due to the needs that arose during the pandemic. The per capita expenditure in the EU was €3,262, and Greece stands at 45% of the EU average and at 57% of the levels of the Southern countries. The public health expenditure per capita was €908 in 2020, compared to €862 in 2019, while in the EU increased to €2,649 and in Southern Countries to €1,905. Thus, public health expenditure per capita in Greece is at 34% of the EU average, compared to 73% in 2009.

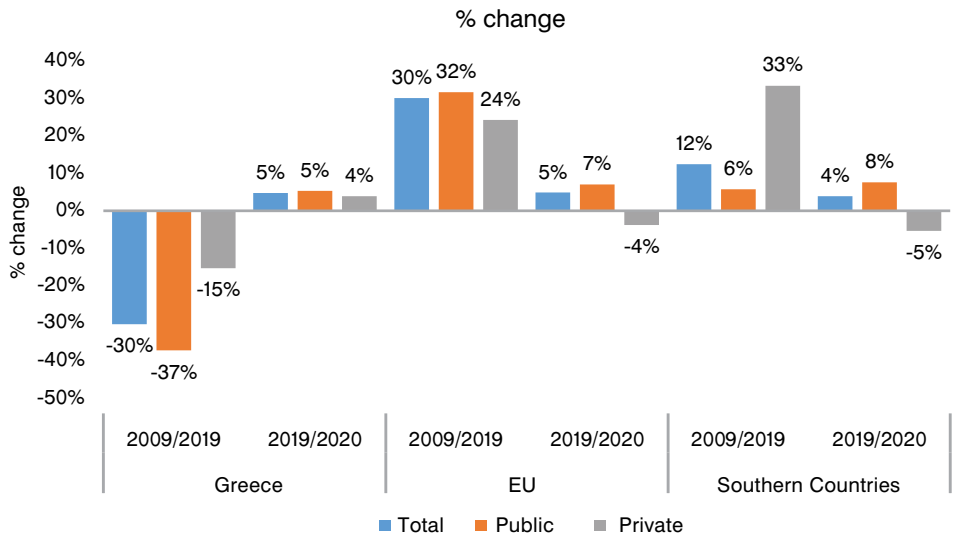
Figure 26: Total per capita health expenditure Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT 2022, OECD Health Statistics, 2022, data processing IOBE Southern countries (Italy, Spain, Portugal).

In the period 2009-2019, health expenditure per capita decreased in Greece by 30%, with a greater decrease recorded in public expenditure per capita (-37%), while in the EU both expenditure per capita and public expenditure increased by 29% the same period. In the Southern Countries, per capita expenditure increased in the period 2009-2019 by 12%, while public expenditure increased by 6%.

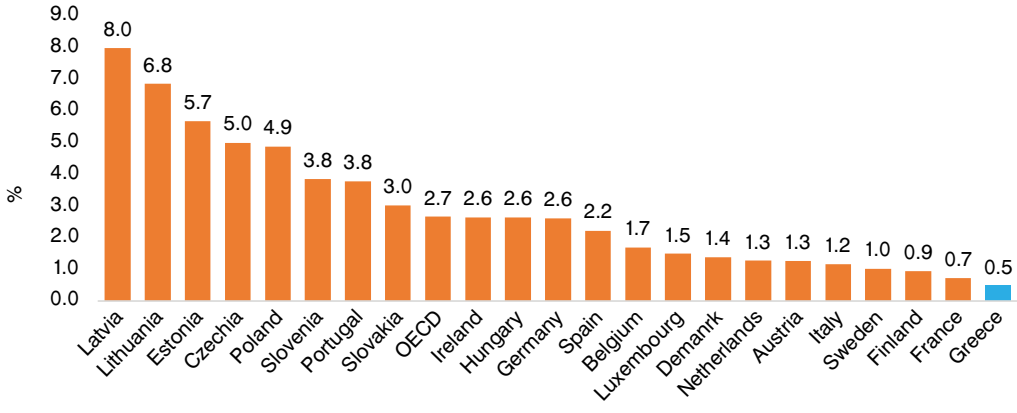
Figure 27: Per capita health expenditure % change - Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT 2022, OECD Health Statistics, 2022, data processing IOBE Southern countries (Italy, Spain, Portugal).

Over the period 2015-2019, the per capita health expenditure in Greece increased by +0.5%, the smaller among OECD countries.

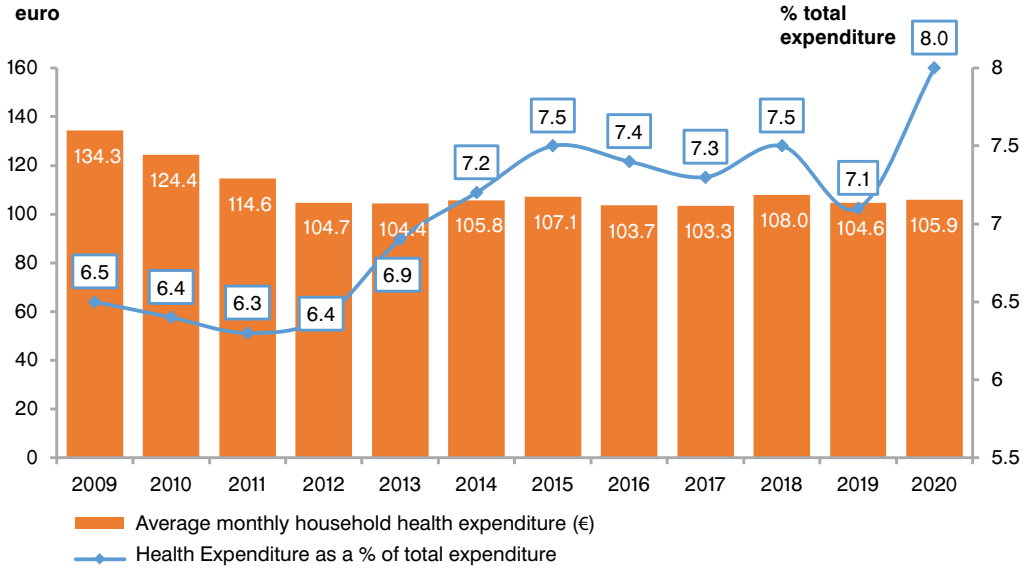
Figure 28: Average per capita health expenditure evolution, OECD counties, 2015-2019



SOURCE: OECD Health Statistics, 2021

Households' monthly health expenditure was contracted by -22.1% during 2009-2020, when it reached €105.9, which accounted for 8.0% of total household expenditure (6.5% in 2009), indicating households' reduced purchasing power and increased participation in health expenditure.

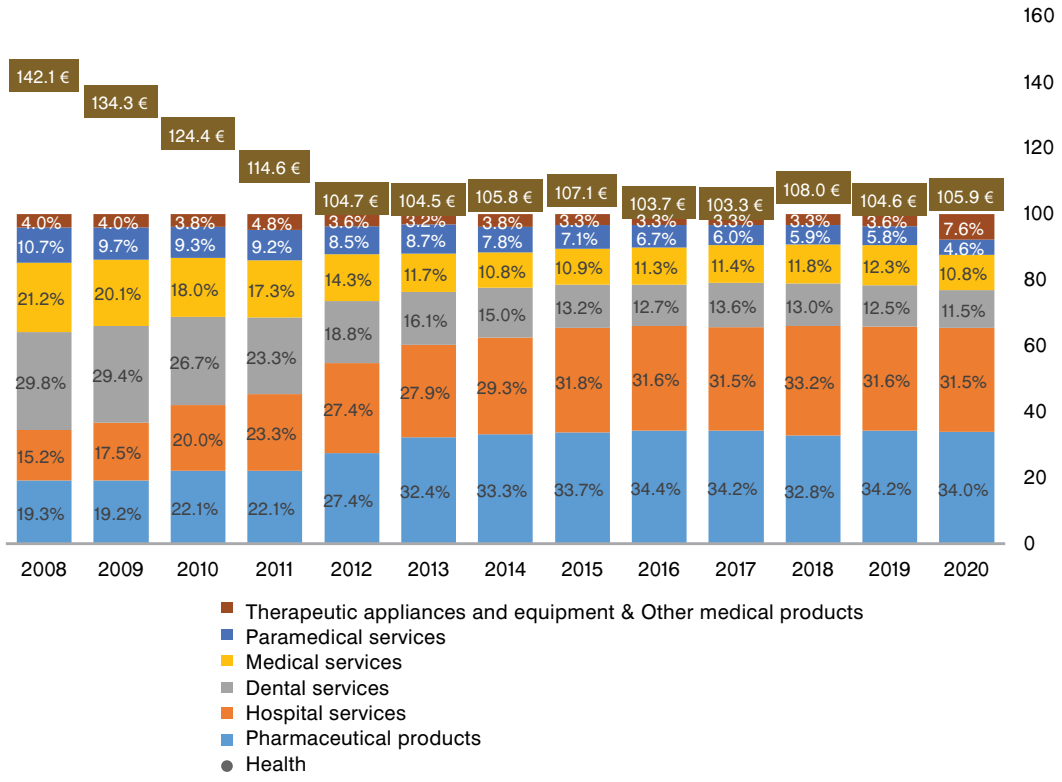
Figure 29: Health expenditure of households (€) per month-Greece



SOURCE: ELSTAT 2021, 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 €105.9 monthly health expenditure per household, 34.0% refers to pharmaceuticals and 31.5% to hospital services, 11.5% to dental services and 10.8% to other medical services.

Figure 30: Breakdown of household health expenditure (%) per month - Greece

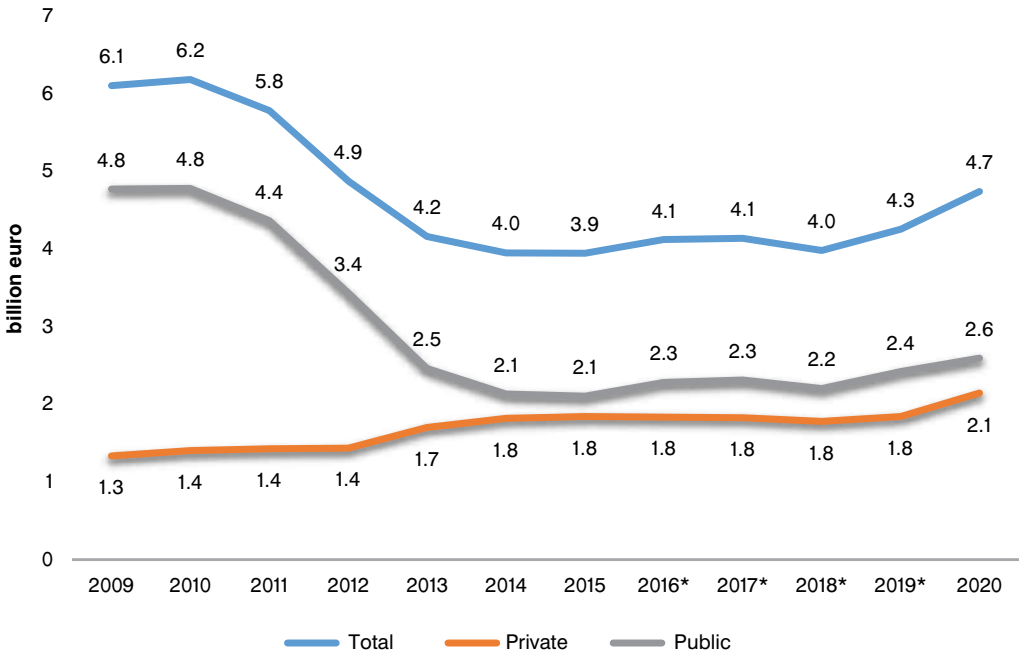


SOURCE: ELSTAT, 2021, data processing IOBE

3.2 PHARMACEUTICAL EXPENDITURE

Total expenditure for pharmaceuticals and other medical non-durable goods accounted for €4.7 bil. in 2020, recording an increase of -22.3% compared to 2009. Correspondingly, public expenditure for pharmaceuticals and other medical non-durable goods from €4.8 bil. in 2009 amounted to 2.6 bil. in 2020, recording a further decline of 45.5%, while private expenditure for pharmaceuticals and other medical non-durable goods increased from €1.3 bil. in 2009 to €2.1 bil. 2020.

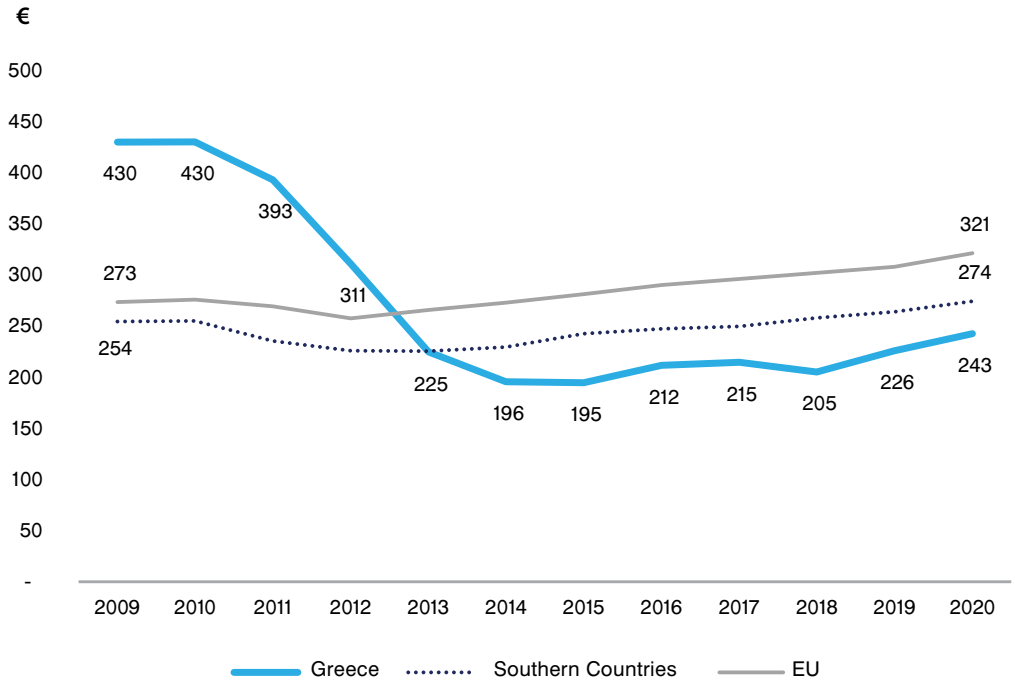
Figure 31: Total expenditure for pharmaceuticals and other medical non-durable goods (bil. €) - Greece



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT, 2022, 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 7). *Revised data

Similarly, a downward trend observed in public per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece, from €430 in 2009 to €243 in 2020. On the contrary in the EU increased from €273 in 2009 to €321 in 2020 approximately €78 higher than Greece.

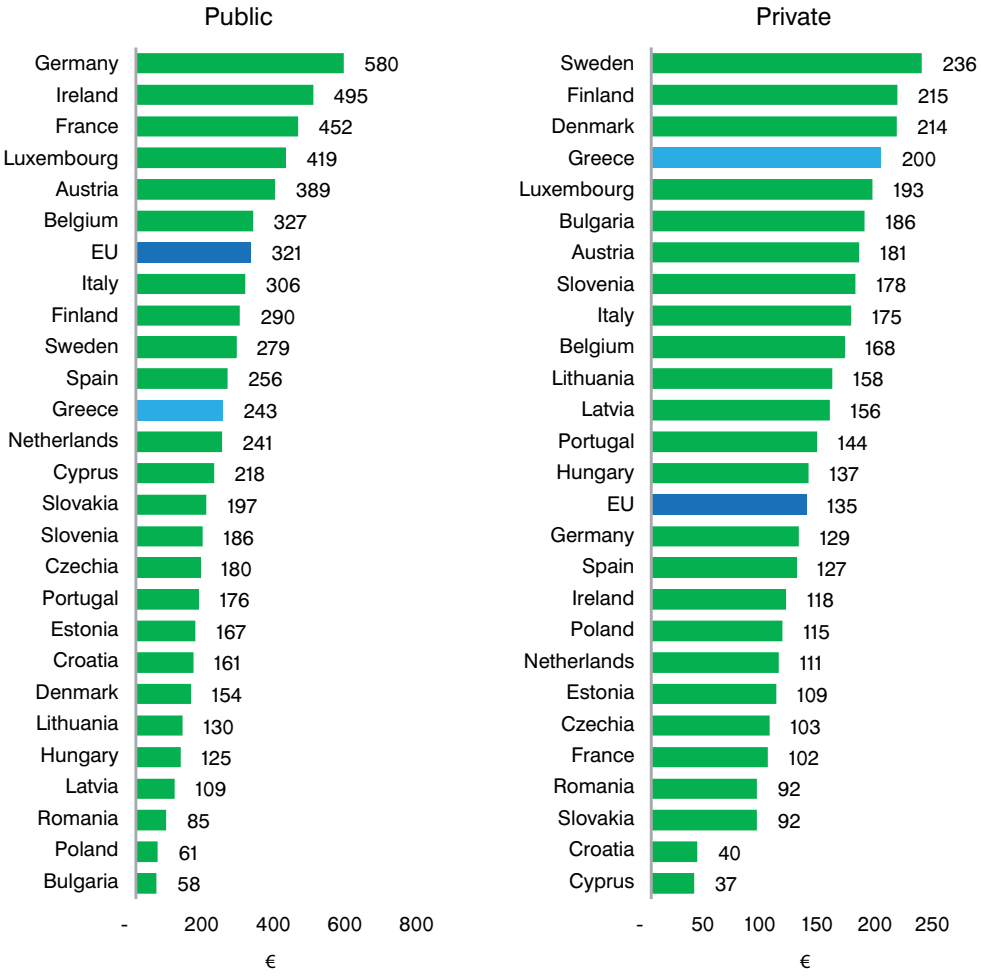
Figure 32: Public per capita expenditure for pharmaceuticals and other medical non-durable goods Greece-EU-Southern countries



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT OECD Health Statistics, 2022, Eurostat 2022, data processing IOBE. Southern countries (Italy, Spain, Portugal).

More specifically, the higher public per capita expenditure in 2020 for pharmaceuticals and other medical non-durable goods was recorded in Germany, Ireland and France, while Greece (€243) is below the average of EU (€321). On the contrary, private per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece (€200) is higher than the average of EU (€135), ranking 4th among EU countries.

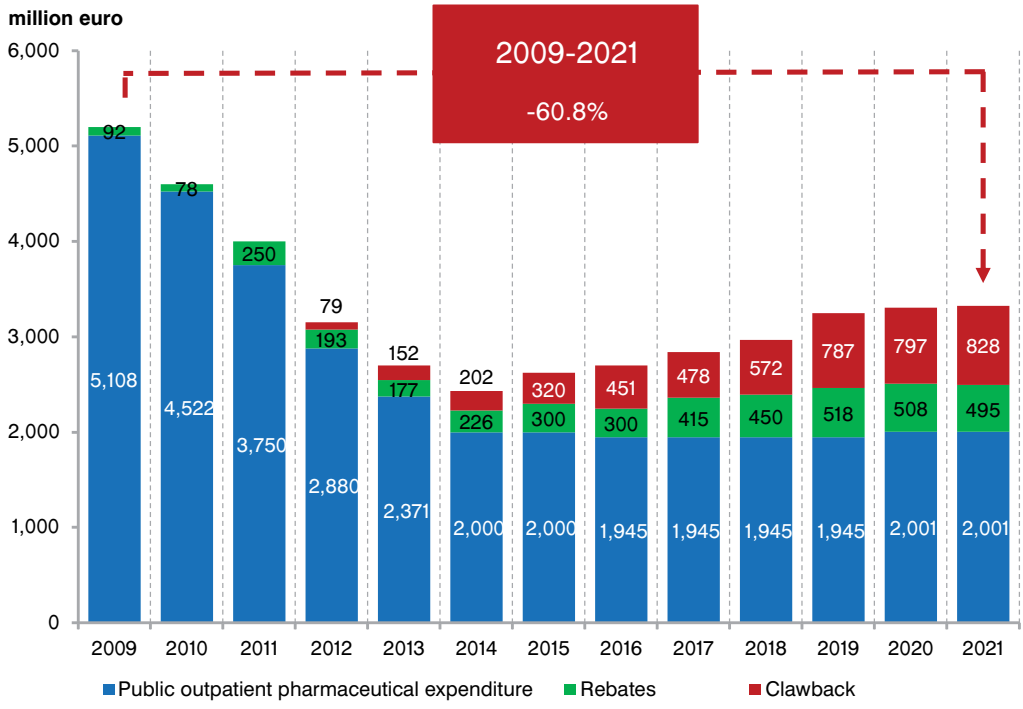
Figure 33: Public & private per capita expenditure for pharmaceuticals and other medical non-durable goods (2020)



SOURCE: System of Health Accounts (SHA) 2020, ELSTAT, OECD Health Statistics, 2022, Eurostat, 2022, data processing IOBE.

Public outpatient pharmaceutical expenditure amounted to €2.0 bil. in 2021 compared to €5.1 bil. in 2009, resulting in an overall decrease by -60.8%. Accordingly, there was a significant increase in the contribution of pharmaceutical industry through mandatory returns and discounts (clawback and rebates). Specifically, in 2021 industry's contribution was €1.3 bil.

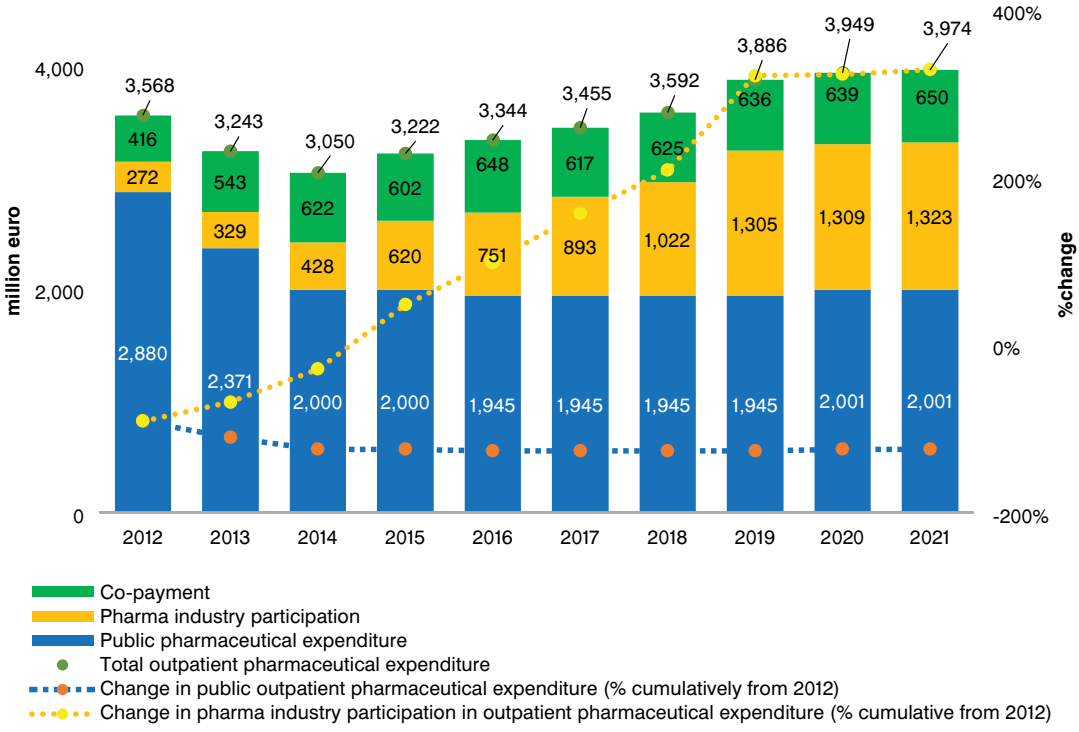
Figure 34: Public Outpatient pharmaceutical expenditure and industry's contribution (excluding patients' contribution)



SOURCE: EOPYY 2012-2020, State Budget 2014-2020, data processing IOBE-SFEE Note: Although the pharmaceutical companies sell at ex-factory prices, the state calculates the clawback at retail prices.

Total outpatient pharmaceutical expenditure (including estimated patients' and industry contribution) surpasses €3.9 bil. in 2021. However, the significant decline in public outpatient pharmaceutical expenditure by 31%, during 2012-2021, resulted in a 386% increase on industry's contribution and in a 56% of patients over the same period.

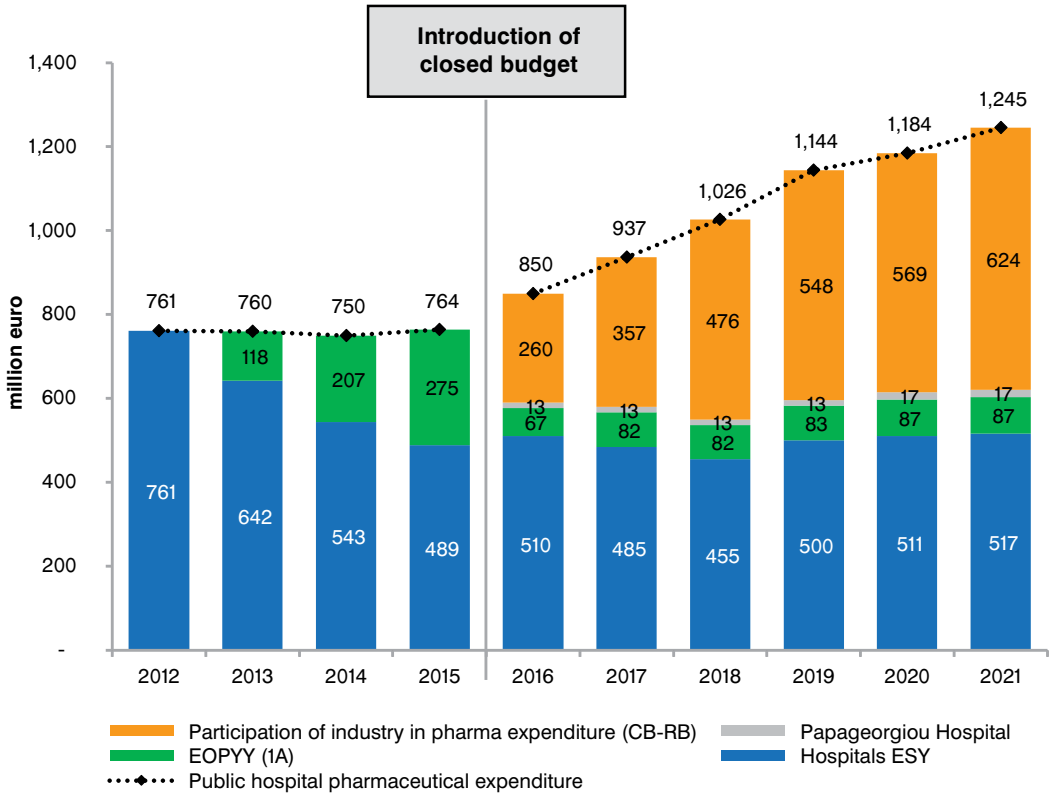
Figure 35: Total outpatient pharmaceutical expenditure



SOURCE: EOPYY 2012-2021, State Budget 2014-2021, data processing IOBE-SFEE Patient participation: What the patient pays to the reimbursed market (i.e. 0%, 10%, 25%) and the burden resulting from the difference between Retail Price - Reimbursement Price.

Public hospital pharmaceutical expenditure was set at €621 mil. for 2021, decreased by -18.7% compared to 2015 (€764 mil.), before introducing closed budget. The reduction of public hospital pharmaceutical expenditure resulted in a shift towards industry through mandatory returns and discounts (clawback and rebates), estimated at €624 mil. for 2021.

Figure 36: Public hospital pharmaceutical expenditure and industry's contribution



SOURCE: EOPYY 2012-2021, ESY.net 2012-2015, data processing IOBE-SFEE. Note: Estimations for 2021 for industry's contribution. EOPYY (1A) include Aretaeio hospital. Industry participation includes clawback & rebates. *For 2021 industry participation is estimation

3.3 PATIENTS' CONTRIBUTION

Public pharmaceutical expenditure includes the expenditure of all the social security funds for prescribed medicines, i.e. medicines that are reimbursed by Social Security Funds (SSF). Net public pharmaceutical expenditure is the final amount paid by the SSFs after deduction of rebates & clawback.

Private pharmaceutical expenditure includes co-payment rates of insured persons for reimbursed medicines (statutory participation & the additional charge incurred when the patient selects a medicine with a higher Retail Price than the Reimbursement Price), the private costs of consumers (patients) for non-reimbursed pharmaceuticals and related products but also for those medicines they pay or choose to pay in full, as well as the reimbursement of part of the expenditure by private insurance companies.

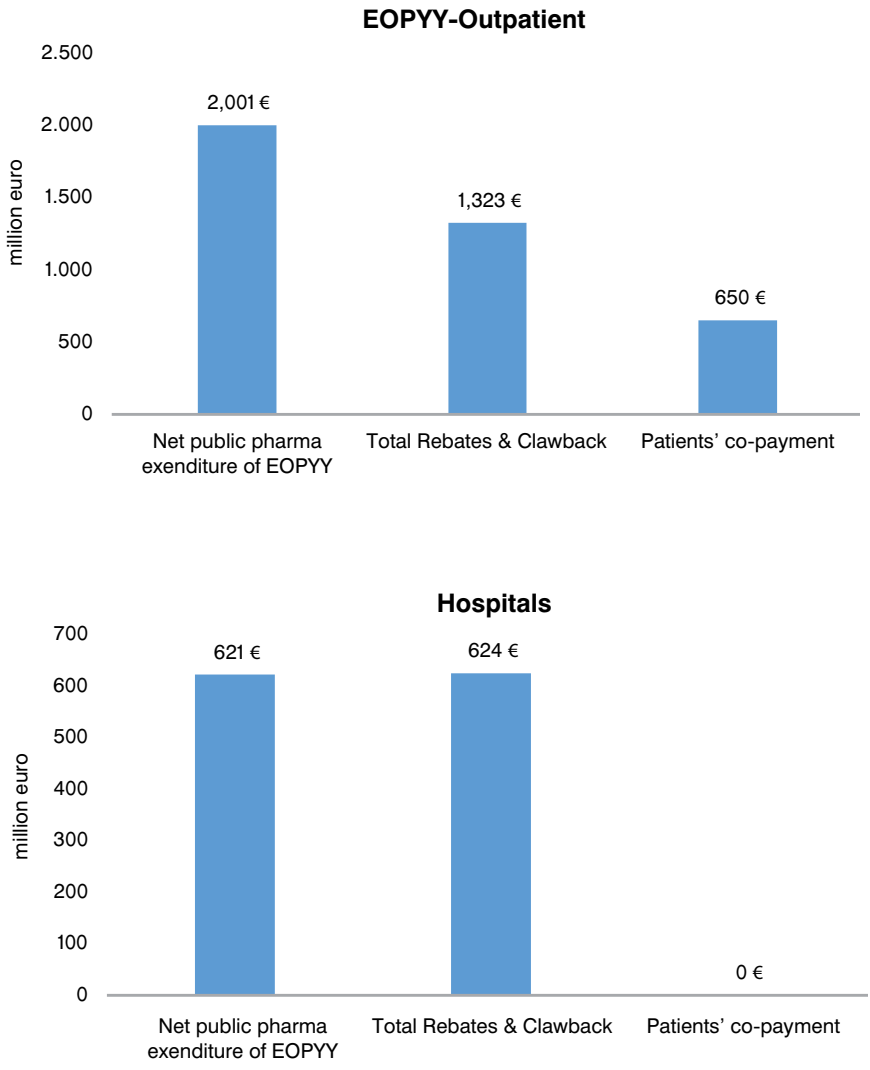
Patient co-payment in reimbursed medicines is distinguished in:

- "Statutory co-payment: 0% or 10% or 25% of the reimbursement price
- Charge resulting from the difference between Retail Price and Reimbursement Price when the patient selects a medicine with Retail Price Higher that the Reimbursement Price

Other private payments for a medicine contain:

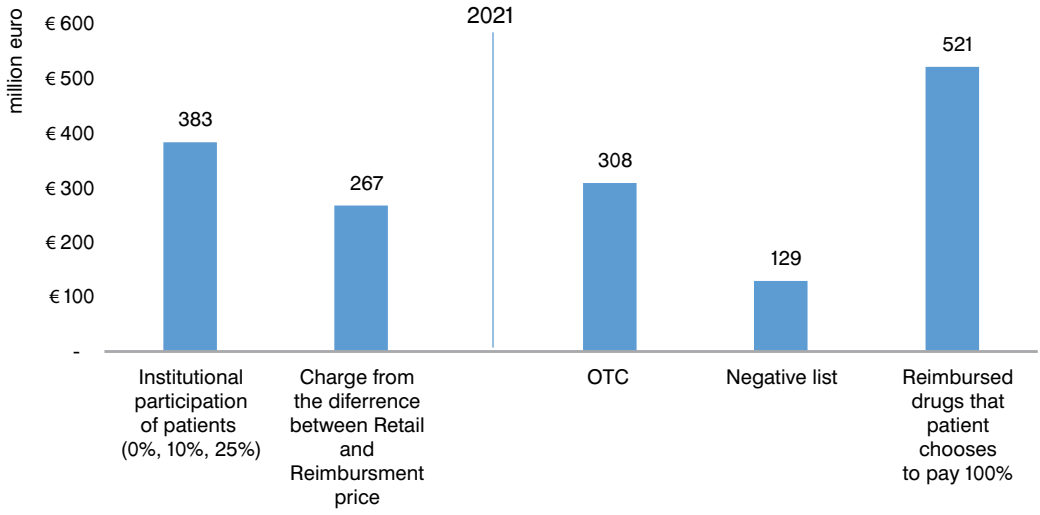
- either non-prescription medicines (OTC)
- either prescribed medicines which are not reimbursed (Negative List)
- either prescribed medicines of the reimbursement list, but the patient chose not to use his insurance right and chose to pay them entirely out of his pocket.

Figure 37: Patient participation in the reimbursement market (2021)



SOURCE: State Budget, company notes, data from IDIKA, data processing SFEE. The data for 2021 of patient participation are estimations.

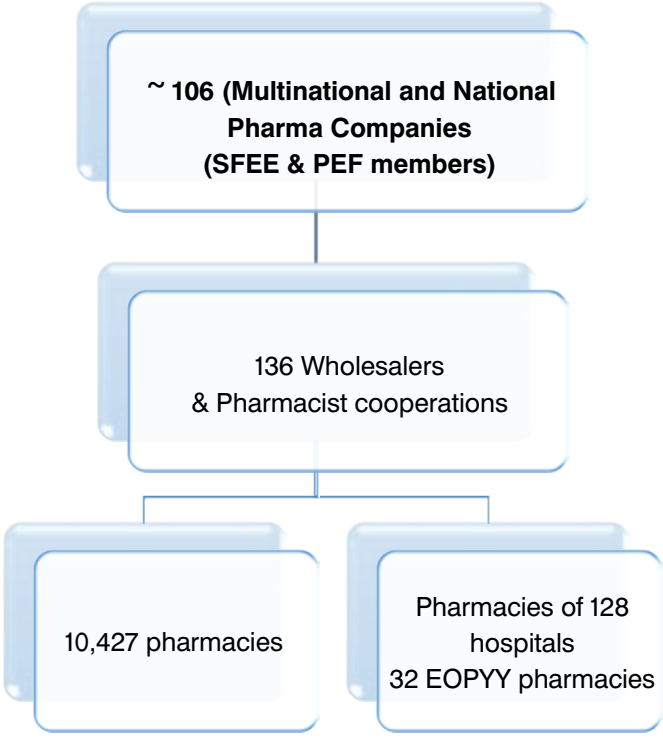
Figure 38: Total private pharmaceutical expenditure (2021)



SOURCE: Data from IDIKA (Institutional Patient Participation), OTC and Negative list, SFEE calculations based on EOPYY and IQVIA (Q4/2021). The data for 2021 of patient participation are estimations.

4.1 SUPPLY CHAIN FOR PHARMACEUTICAL PRODUCTS IN GREECE

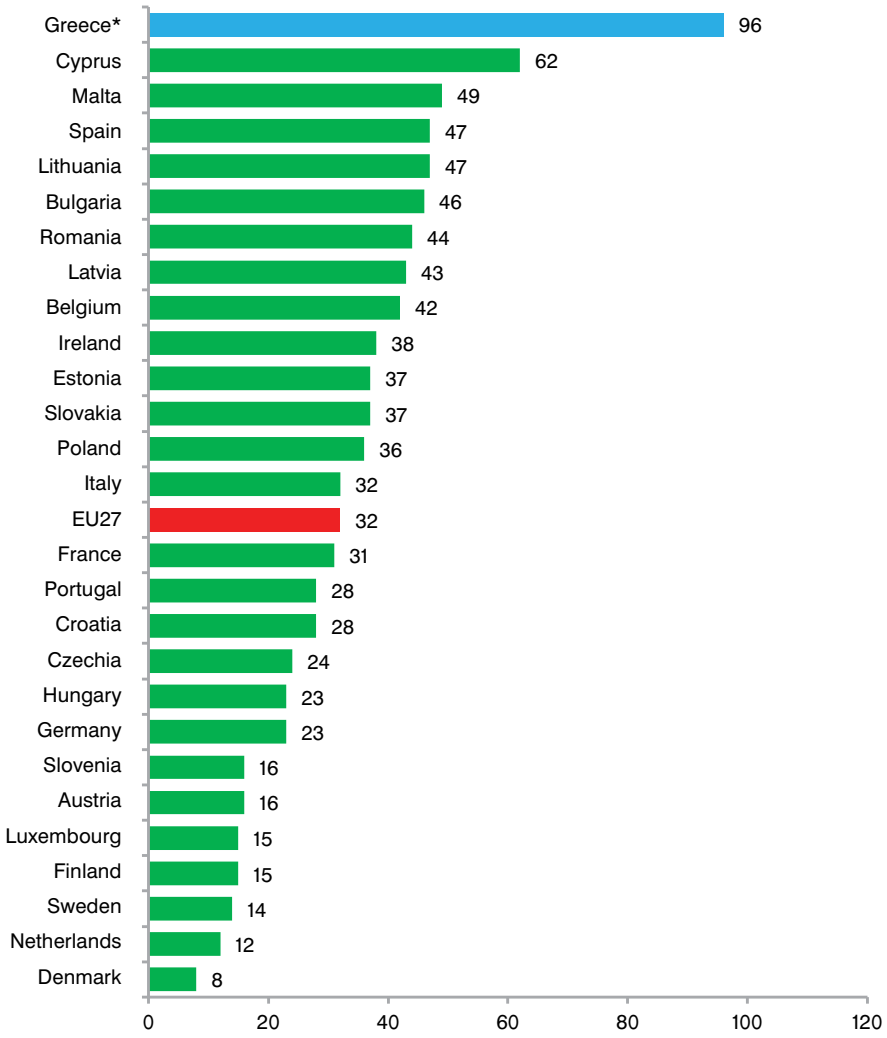
The production and distribution of pharmaceuticals is one of the most dynamic sectors in the Greek industry. Supply chain for pharmaceutical products is comprised of pharmaceutical companies (both manufacturers and importers), wholesalers (both storage and distribution) and pharmacies. More specifically,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



SOURCE: ELSTAT, EOPYY, PanHellenic Association of Pharmaceutical Wholesalers

With a pharmacy density of 96 pharmacies per 100.000 inhabitants, Greece comes first in 2020 among the EU-27 average of 32 pharmacies per 100.000 inhabitants.

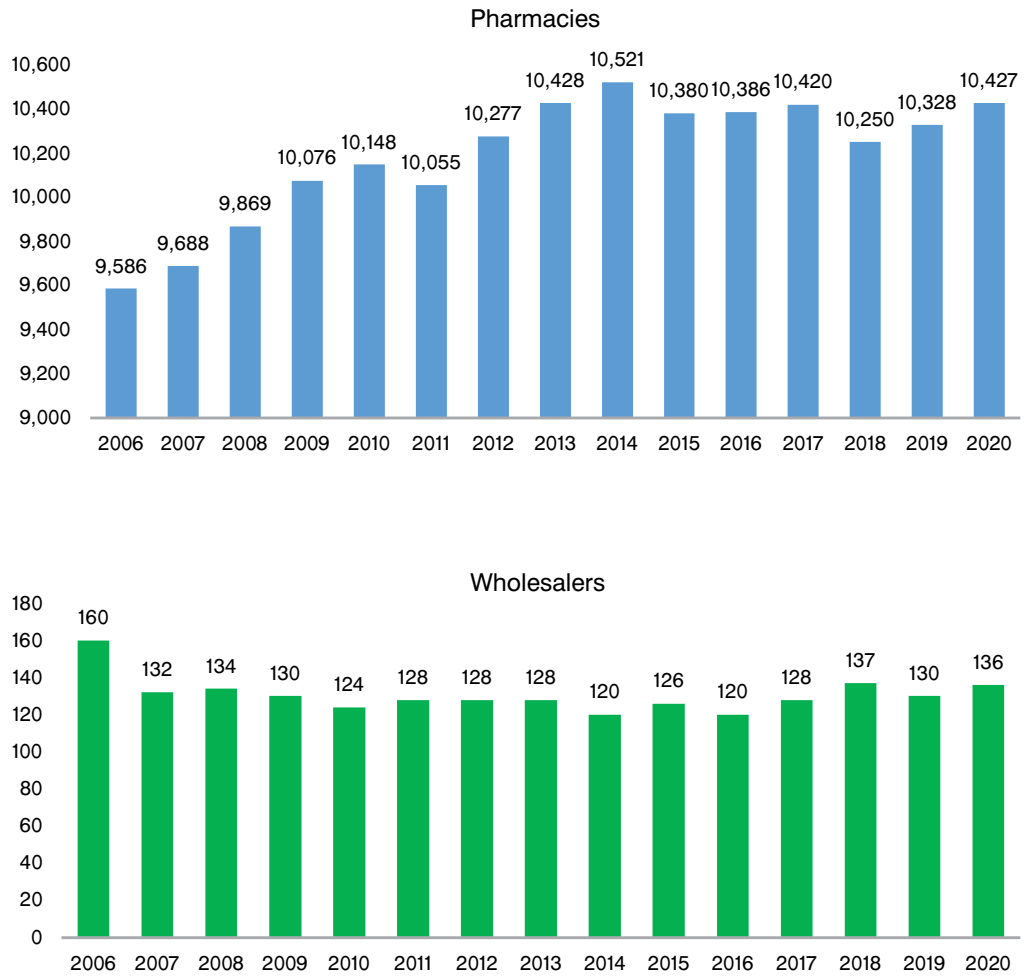
Figure 39: Number of pharmacies per 100,000 inhabitants, EU27 (2020)



SOURCE: ABDA. German Pharmacies, Figures Data Facts 2021, ELSTAT., 2021 * Data for Greece come from the latest available ELSTAT. data.

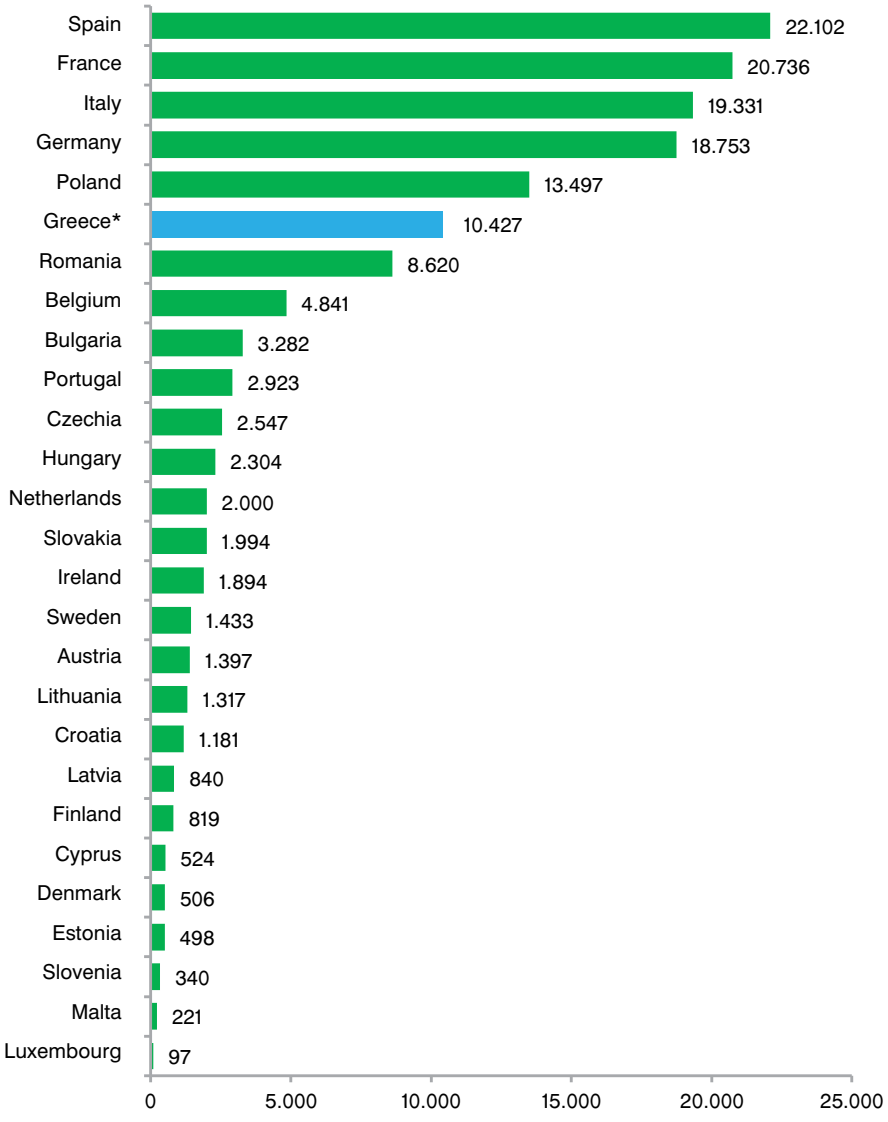
In 2020, 10,427 pharmacies operated in Greece, out of which 3,674 pharmacies (35.2%) were in the Region of Attika. The number of wholesalers increased from 130 in 2019 to 136 in 2020.

Figure 40: Pharmacies and wholesalers- Greece



SOURCE: ELSTAT, 2021

Figure 41: Pharmacies EU27-Greece (2020)



SOURCE: ABDA, German Pharmacies, Figures Data Facts 2021, ELSTAT,2021 . * Data for Greece come from the latest available ELSTAT

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, 32 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, most high-cost drugs (N.3816 / 2010) provided by the EOPYY pharmacies and hospital pharmacies.

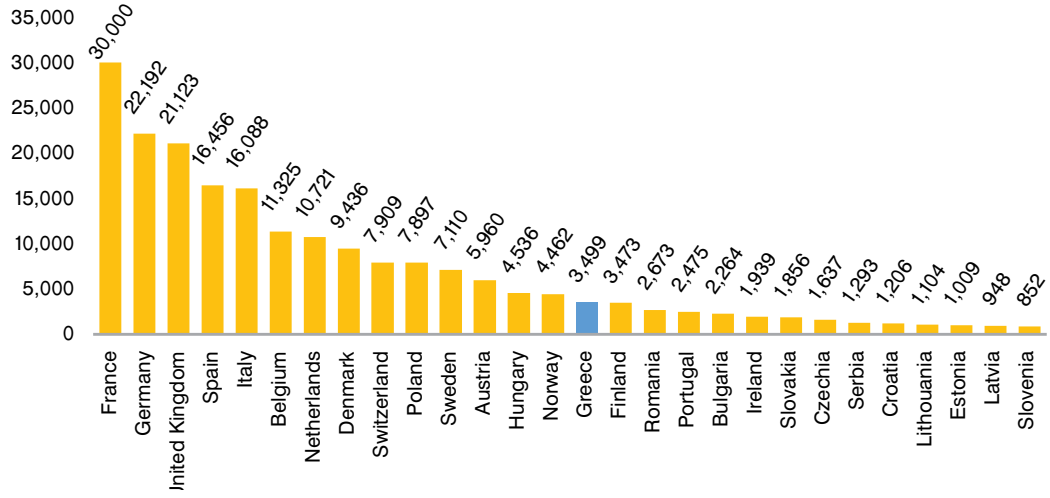
Since January 2016, under the new legislative regulation for hospital clawback (N. 4354 / 12.16.2015, Section D, Article 41), all high-cost medicines that their use is hospital only (Annex 1A) are exclusively administered from pharmacies in public hospitals.

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

4.2 RESEARCH AND DEVELOPMENT (R&D)

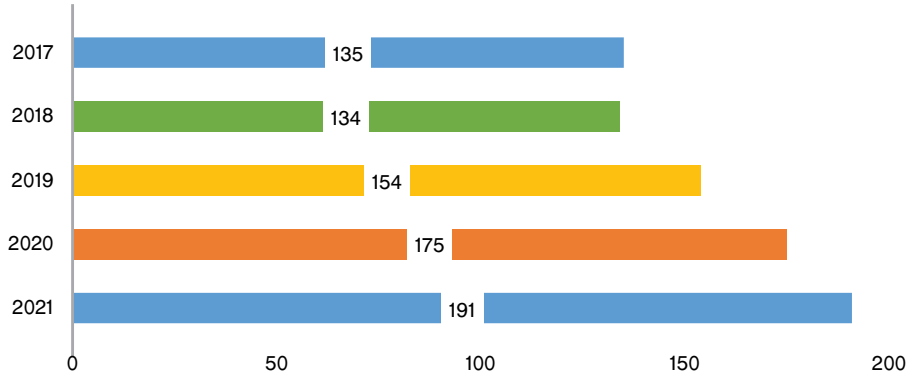
In Greece, 3,499 clinical studies (2,000 completed) were conducted from 2002 up to 2021 (all types and phases).

Figure 42: Total number of clinical trials, all phases and stages (2002-2021)



SOURCE: Clinical trials.gov, 2021

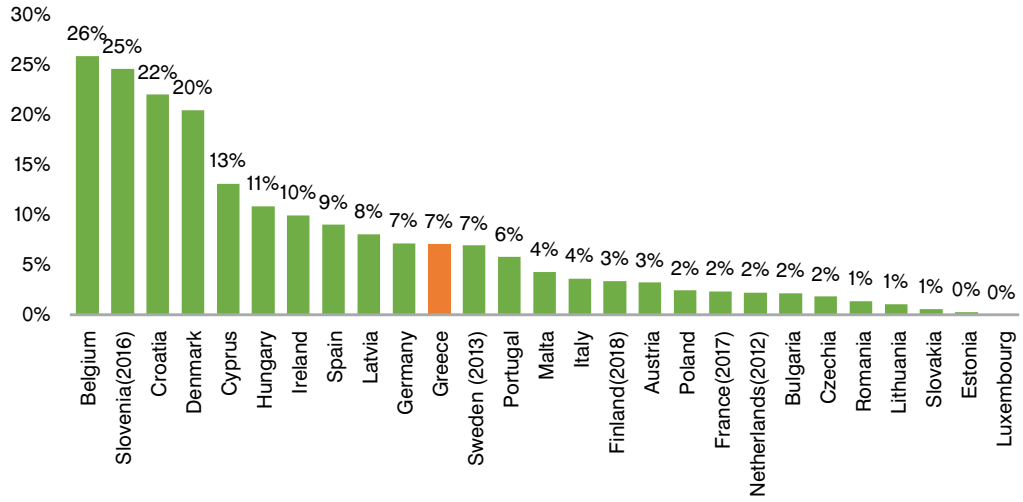
Figure 43: Number of clinical trials by phase and year, Greece (2017-2021)



SOURCE: SFEE

Research & Development expenditure in the pharmaceutical industry which reached €76 mil. (€51 mil. In 2017) accounts for 7% of total R&D expenditure in Greece in 2019, share higher than 2017 (5%).

Figure 44: Pharmaceutical R&D expenditure (% of total R&D expenditure) (2019)

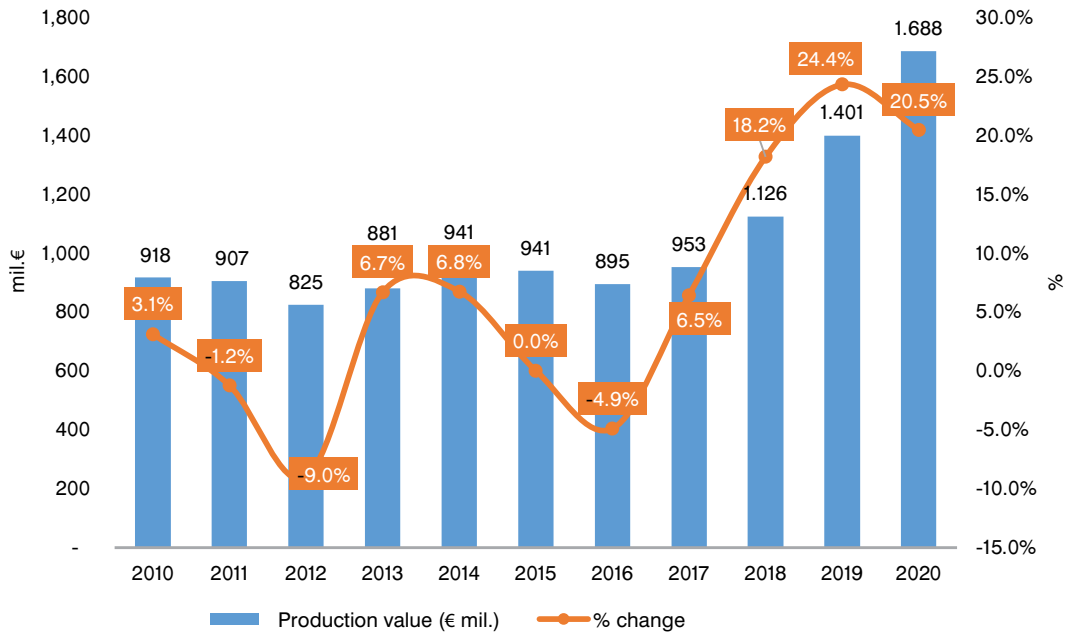


SOURCE: Eurostat, 2022, data processing IOBE

4.3 PRODUCTION

According to Prodcom database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece was estimated at €1.7 bil. in 2020, increased by €287 million compared to 2019, while compared to the average of the period 2010-2017 (€907 million) it is higher by 82%.

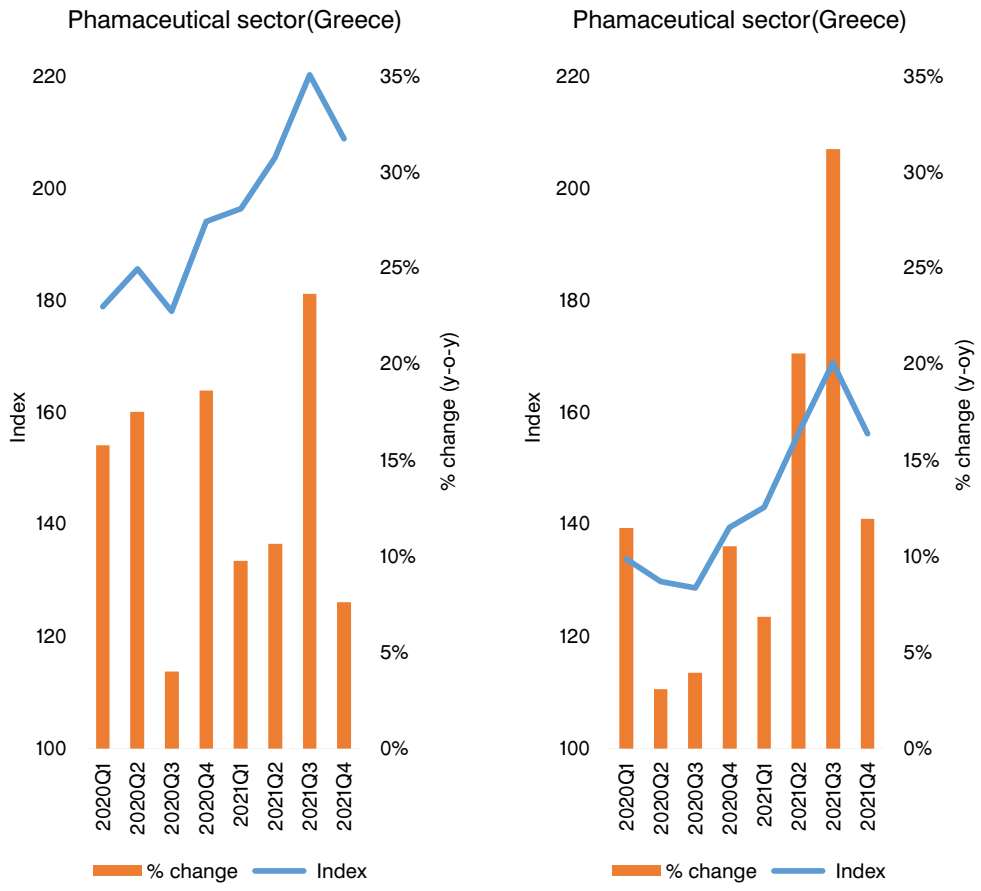
Figure 45: Production of pharmaceutical products (mil. €)



SOURCE: Eurostat 2022, PRODCOM Database, data processing IOBE. *Any changes based upon review of data from Eurostat

The index of industrial production of pharmaceutical products recorded continuous increases from the first quarter of 2020 to the end of 2021, resulting in the fourth quarter of 2021 standing at 208 units, despite the double decline of 2015. The production index in the EU27 average had a similar course, while it stands at 156 units in the fourth quarter of 2021, i.e. it is 56% higher compared to 2015. Overall, in 2021 the index in Greece is 13% higher compared to 2020, following the same increase in 2020 (+14%), while in the EU27 the index increased overall in 2021 by 17%.

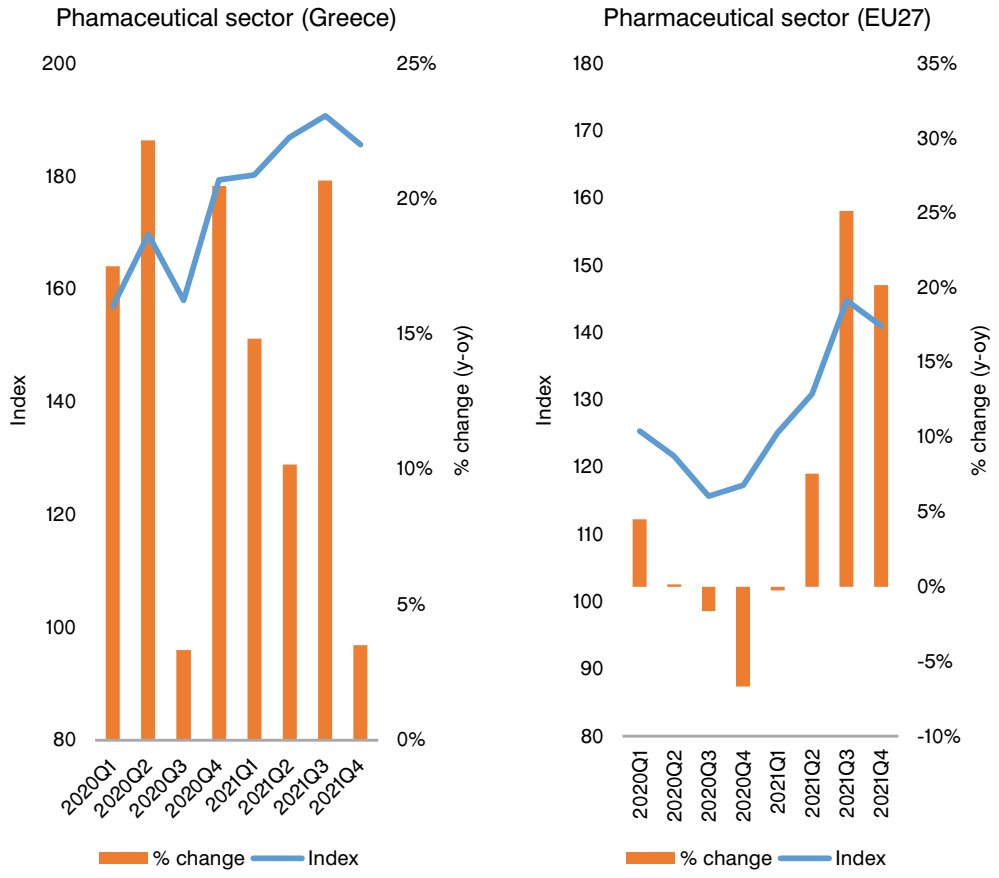
Figure 46: Industrial index of domestic pharmaceutical production (2015=100)



SOURCE: Eurostat, 2022, seasonally adjusted and adjusted data by working days, data processing IOBE

The turnover of pharmaceutical has been continuously increasing since the beginning of 2020 and stands at 185.7 units in the fourth quarter of 2021, compared to 141 units in the EU27. It is noted that the turnover index in the EU27 recorded a decrease at the end of 2020. In 2021, the index has increased by 12% in Greece and 13% in the EU27.

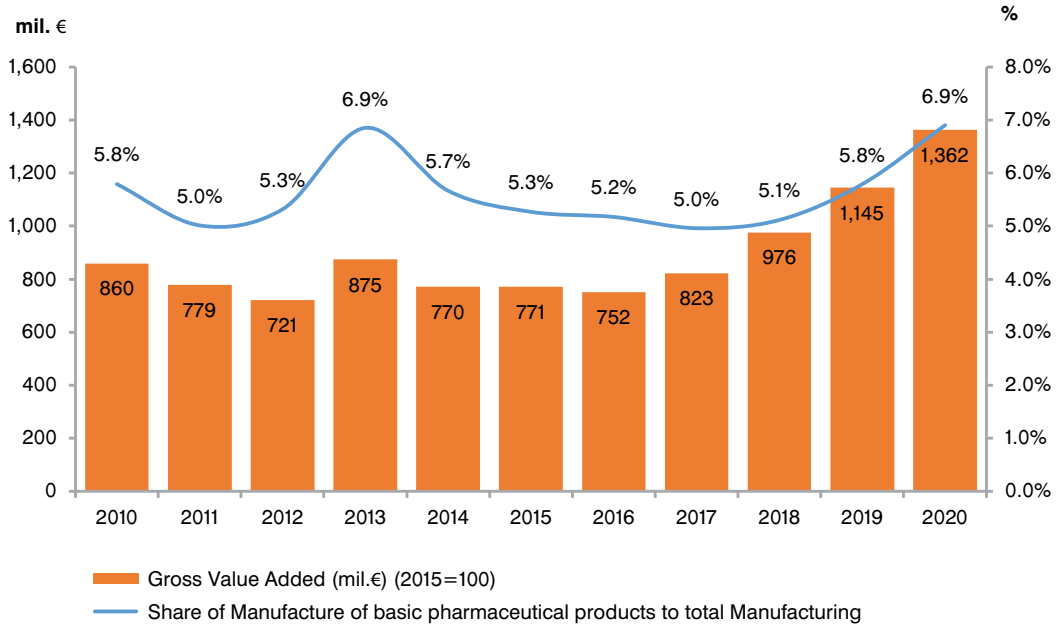
Figure 47: Turnover index in domestic pharmaceutical production (2015=100)



SOURCE: Eurostat, 2022, seasonally adjusted and adjusted data by working days, data processing IOBE

The gross Value Added (GVA) of domestic pharmaceutical sector is estimated at €1.36 bil. in 2020, amounted with a share of 6.9% in total manufacturing sector in national accounts terms, showing an upward trend since 2017.

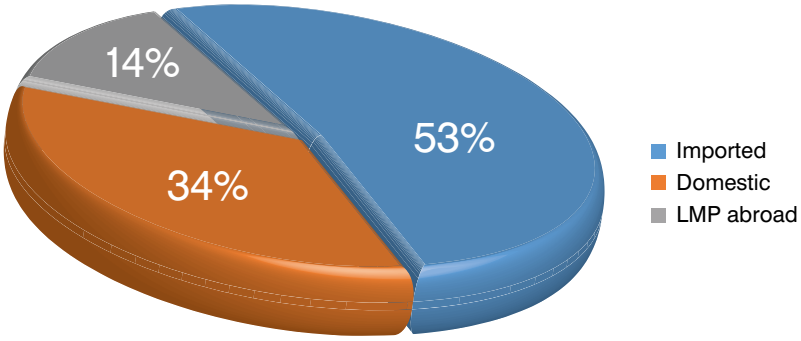
Figure 48: Gross Value Added of pharmaceutical production and share in manufacturing (%)



SOURCE Eurostat, 2022, data processing IOBE*Any changes based upon review of data from Eurostat* C21: Manufacture of basic pharmaceutical products and pharmaceutical preparations include only the companies active in the production of medicines and pharmaceutical preparations. In C21 manufacturing companies are not included firms that belong to subsector 46.46 Wholesale of pharmaceutical products.

Strengthening co-operation between international and domestic factories is a key pillar of the country's pharmaceutical sector activity. Specifically, 34% of pharmaceuticals are produced in domestic factories and in certified production facilities with high-educated personnel, while with appropriate incentives, domestic production of international pharmaceutical products may increase.

Figure 49: Percentage of pharmaceutical production in Greece and abroad (in market volume)

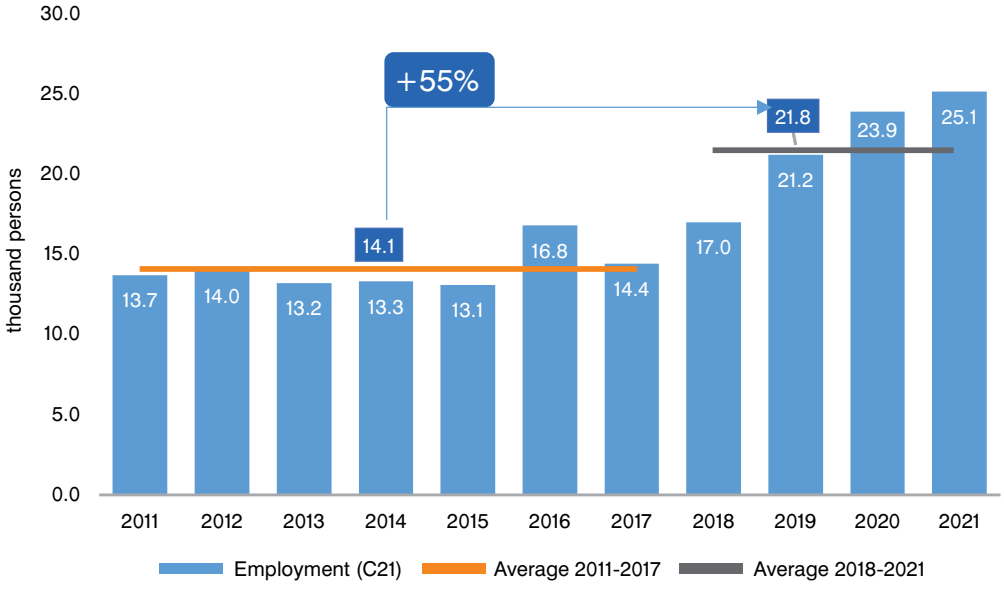


SOURCE: IQVIA FY 2021, *Locally Manufactured products LMP abroad = Products of international companies manufactured / packaged in Greece * Factories: 28 Greek-owned factories and 1 foreign-owned factory

4.4 EMPLOYMENT

In Greece 25.1 thousand people were employed in production of pharmaceutical products and pharmaceutical preparations in 2021, recording a significant increase from 2018 onwards. demonstrating an increase of 9.8% compared to 2019. Employment is at 21.8 thousand on average over 2018-2021, 55% higher compared to 2011-2017 average.

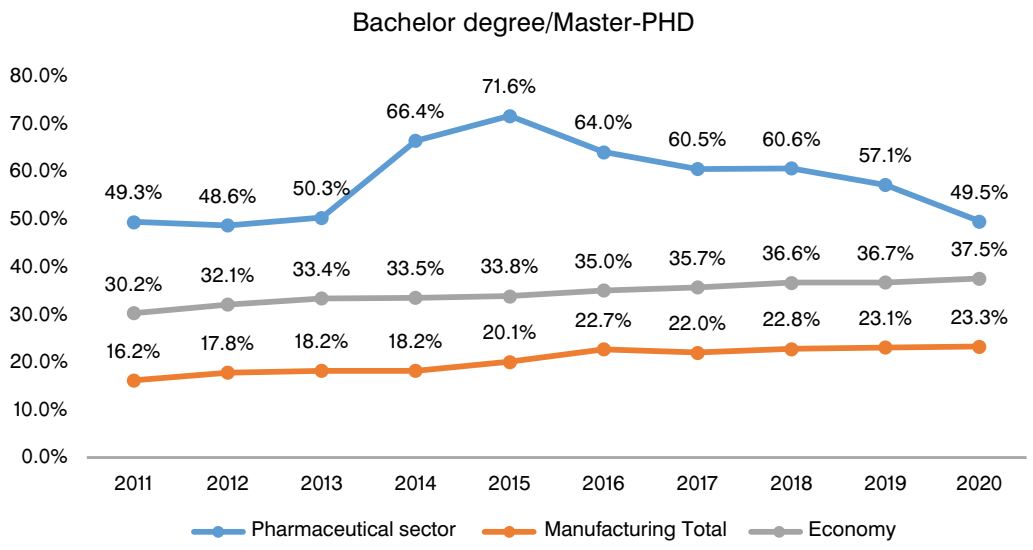
Figure 50: Employment in pharmaceutical production thousand persons



SOURCE: Eurostat, Labour Force Survey, 2022, Employment of persons aged +15data processing IOBE * Data for sectors 21.1 Manufacture of basic pharmaceutical products and 21.2 Manufacture of pharmaceutical preparations are included, 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 2020, the educational background of people working in the pharmaceutical industry was high, with 49.5% of total employees in pharmaceutical production with university education compared to 37.5 % in the manufacturing and 23.3%, in the total economy, indicating the high educational training of the employees in the pharmaceutical industry.

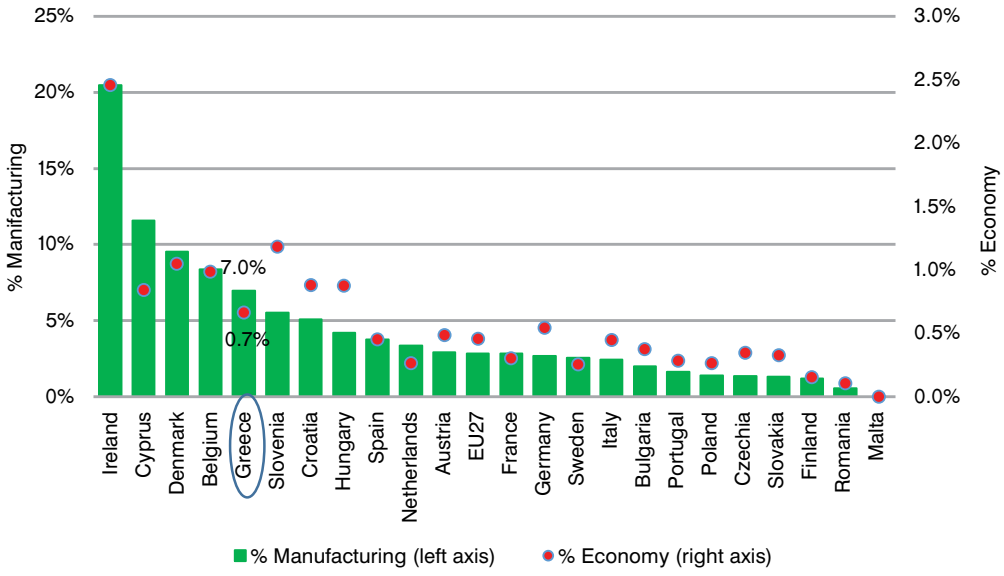
Figure 51: Number of employees with tertiary education in pharmaceutical production (%)



SOURCE: ELSTAT, 2021, Employees Tertiary Education of total employment International Standard Classification of Education (ISCED 2011), data processing IOBE.

In 2021, employment in the pharmaceutical sector represents 0.7% of total employment of the Greek economy, while this share increases to 7.0% with regards to employment in the manufacturing overall. The share of manufacturing is higher than the respective average in EU27 (2.9%).

Figure 52: Employment in the production of pharmaceutical products (% shares in manufacturing and economy) EU27 (2021)



SOURCE: Eurostat. Labour Force Survey 2022, 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 an increase of employment in FTEs by +18.5% during 2015-2020 compared to 4.7% to total manufacturing, indicating that employment in pharmaceutical sector shows inflexibility. In the total economy, employment in Full Time Equivalent (FTE) contacted by 4.1% in the same period.

Table 1: Change in employment and wages 2015-2020

	Employment % change (FTE)	Compensation of employees	Average hourly wage (2020)
Total Economy	-4.1%	7.2%	6.0 €
Manufacturing	4.7%	13.1%	7.9 €
Pharmaceutical production	**18.5%**	**38.2%**	**16.4** €

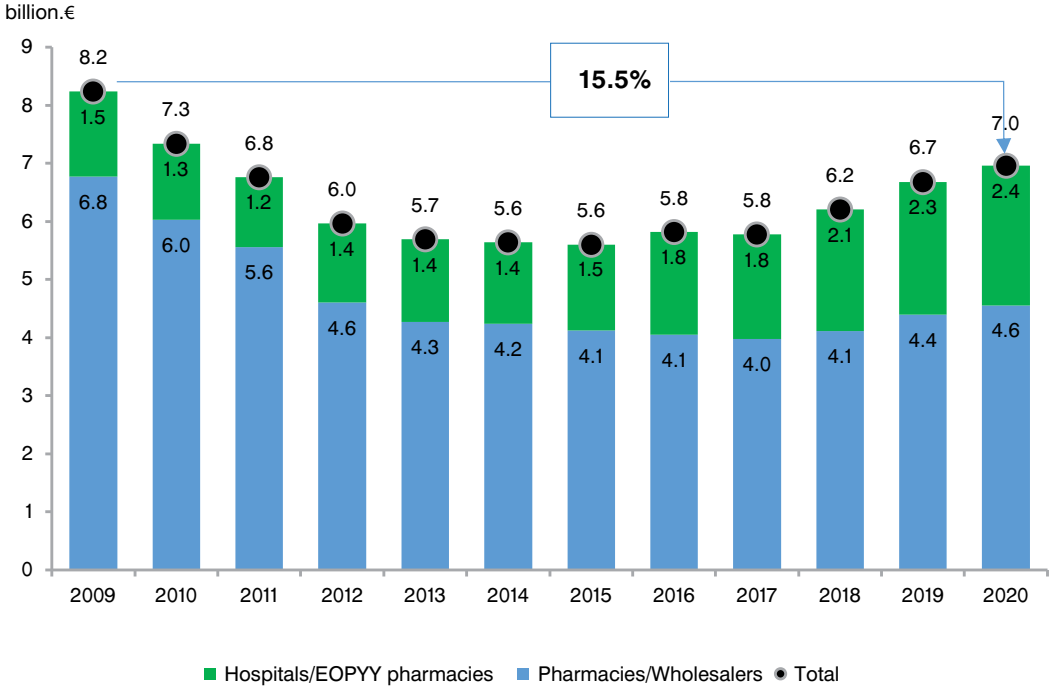
SOURCE: Eurostat, National Accounts, 2022, data processing IOBE

Simultaneously, total wage cost in pharmaceutical industry increased by +38.2% compared to 13.1 in manufacturing and 7.2% in total economy. The higher increase in wage costs compared to the increase in employment is an indication that the pharmaceutical industry is integrating highly paid employees, a feature which is also associated with the high educational background, full time and other characteristics of employees in the industry. The average hourly wage in the sector is double (€16.4) compared to manufacturing (€7.9) and almost triple compared to total economy (6.0).

4.5 SALES

Sales of pharmaceutical products to pharmacies & wholesalers (in values) amounted to €4.6 bil. in 2020 showing an increase of +3.7% compared to 2019. Similarly, sales to hospitals & EOPYY pharmacies amounted to €2.4 bil. in 2020 presenting an increase of +5.0% compared to previous year while compared to 2009 are decreased by 15.5%. In the last 4 years, the share of sales in pharmacies/pharmacies approaches 66%, compared to 77% in the period 2009-2016

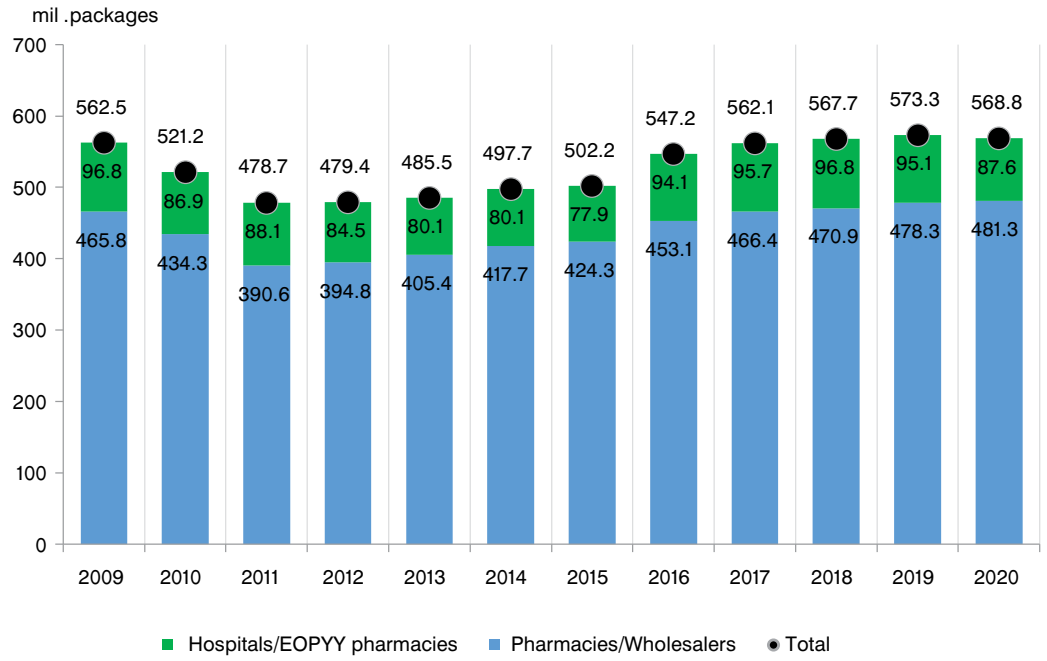
Figure 53: Sales of pharmaceutical products in values (bil. €)-Greece



SOURCE: EOF, 2022 (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 2020 were €427 mil. and are included here.

Regarding the number of packages, a slight decrease by -0.8% was recorded in 2020 compared to 2019 (569 mil. packages) with an increase of 0.6% in pharmacies/wholesalers and a decrease of 7.9% in hospitals/EOPYY pharmacies was depicted.

Figure 54: Sales of pharmaceutical products in volume (mil. packages) - Greece

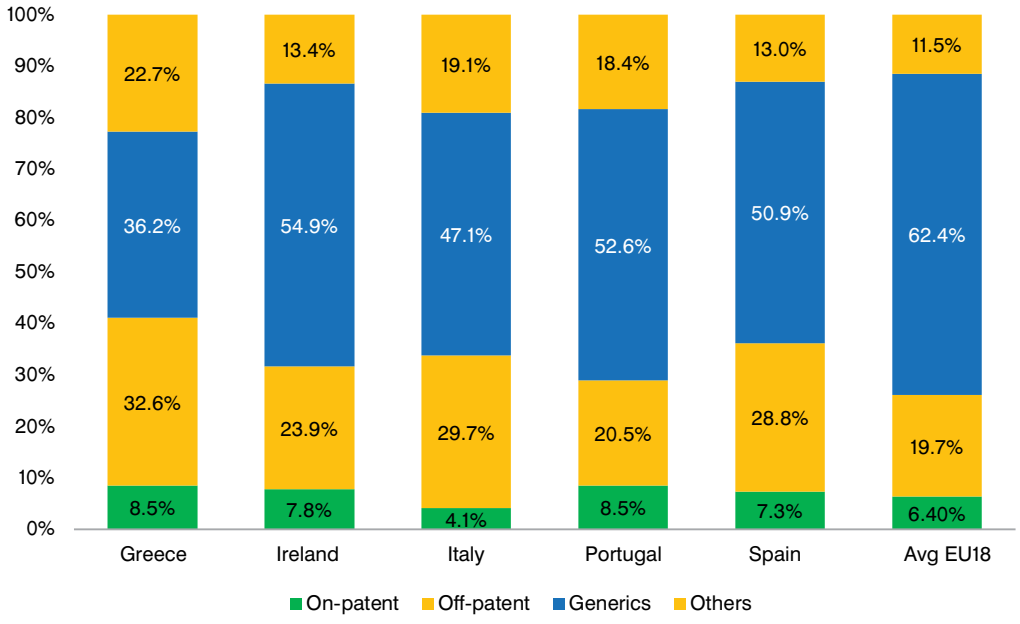


SOURCE: EOF, 2022 *Possible smaller packaging replacements.

Pharmaceutical products can be classified according to their patent protection status. According to IQVIA (Q4 2021), the penetration rate of patent protected medicinal products (on patent) in terms of volume account for 8.5% of the market, which is higher than the average of EU18 (6.4%) which can be partly justified by their significantly lower prices in Greece compared to EU18 countries (€0.94 per unit on average compared to €2.02)

Respectively, the market share of non-protected pharmaceutical products amounted to 68.8% (off- patent 32.6% & generics 36.2%). It is worth noting that the penetration rate of off-patent is higher than the average of EU18 (19.7%), while penetration rate of generics is much lower than the average of EU18 (62.4%).

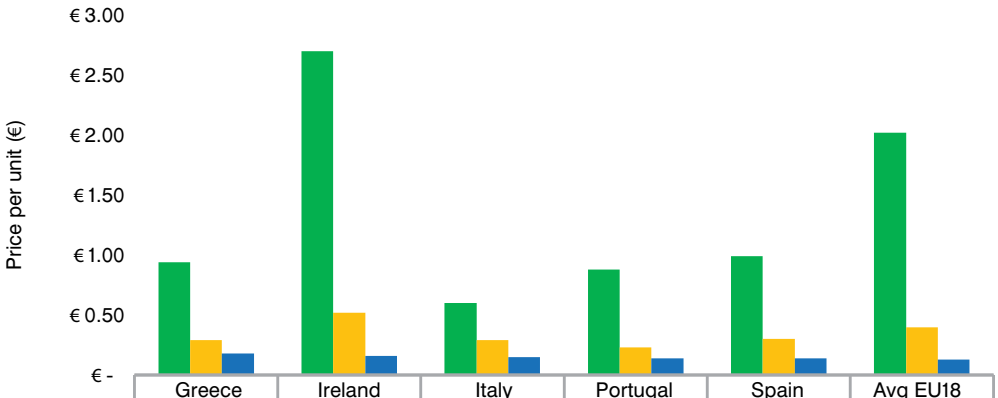
Figure 55: Penetration of pharmaceuticals in EU18, 2021 (in volume) based on patent status



SOURCE: IQVIA, Q4/2021, Note1: only retail sales are included for all countries 2 The 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, Czechia, Hungary, Poland and Slovakia.

According to IQVIA (Q4 2021), 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 (€0.29 per unit compared to €0.40) and by slightly higher prices for generic products in Greece compared to the average of EU18 (€0.18 per unit compared to €0.13).

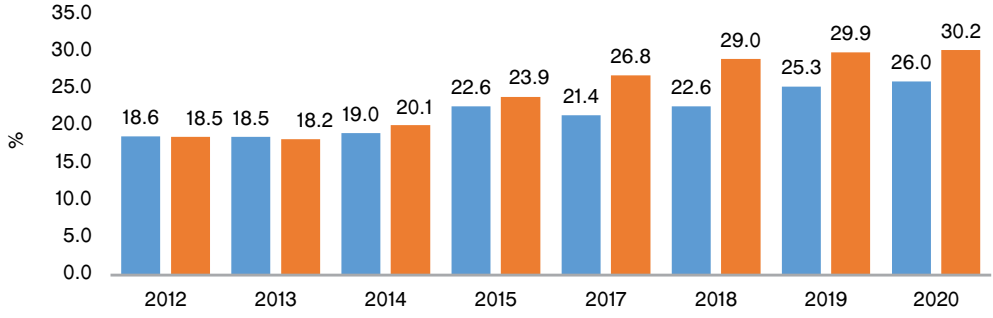
Figure 56: Pricing of pharmaceuticals in EU18, 2021 (price per unit. €) based on patent status



	Greece	Ireland	Italy	Portugal	Spain	Avg EU18
On-patent	€ 0.94	€ 2.70	€ 0.60	€ 0.88	€ 0.99	€ 2.02
Off-patent	€ 0.29	€ 0.52	€ 0.29	€ 0.23	€ 0.30	€ 0.40
Generics	€ 0.18	€ 0.16	€ 0.15	€ 0.14	€ 0.14	€ 0.13

SOURCE: IQVIA, Q4/2021, Note1: only retail sales are included for all countries 2 The 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, Czechia, Hungary, Poland and Slovakia

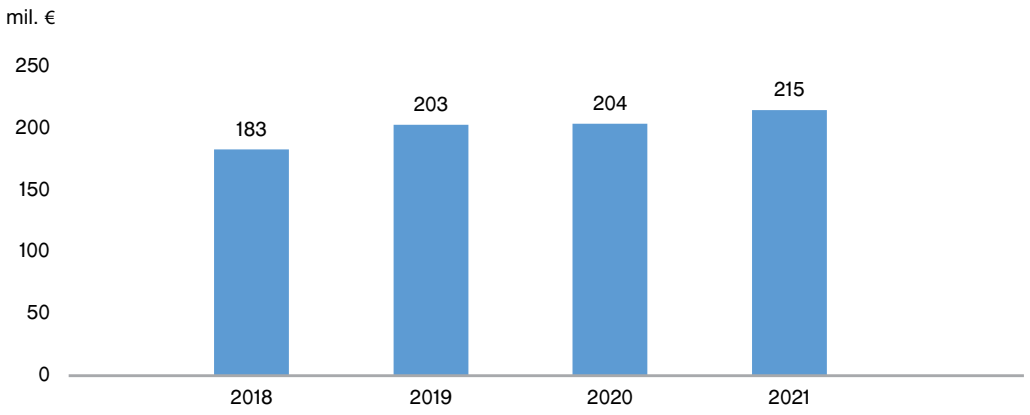
Figure 57: Share of generics -Greece value-volume (2012-2020)



SOURCE: OECD Statistics 2022

The market of OTC in value followed an upward trend from 2018 onwards, from €183 mil. in 2018 reached €215 million in 2021, an increase of 17.5%.

Figure 58: OTC sales in value (in mil. €)



SOURCE: EFEX

The general Distribution Medicines (GEDIFA), a subset of OTC (216 of the total 1,582 OTC), are available outside pharmacies and concern analgesics, antipyretics, antipruritic, topical medications, laxatives (to treat constipation) and mouthwashes.

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

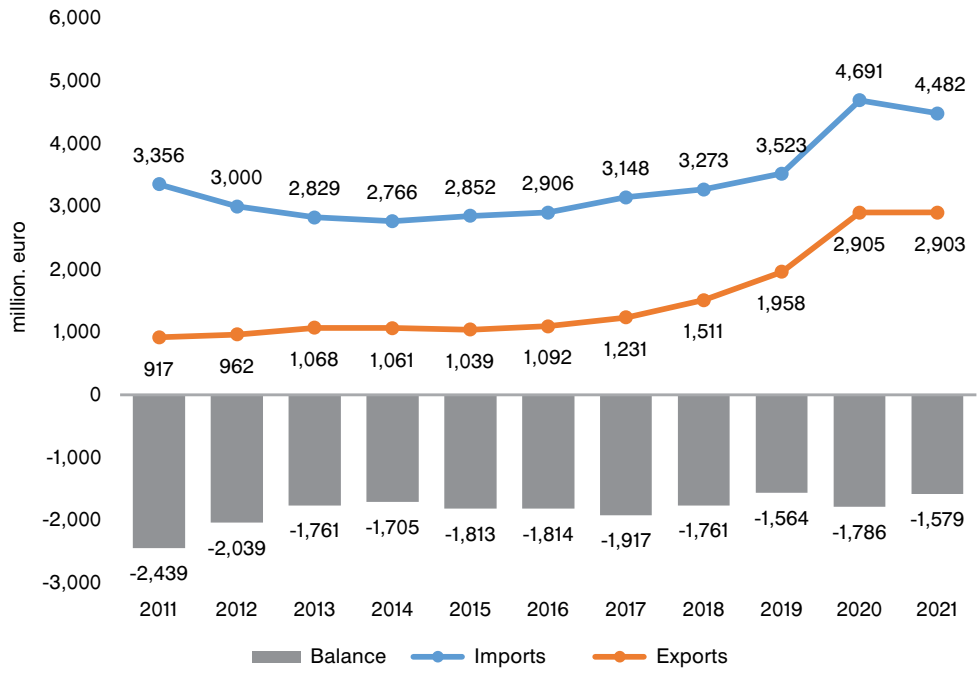
Category	2018	2019	2020	2021
Self-medication (exclude OTC)	150	167	167	180
Food supplements	86	91	106	116
Infant Nutrition	30	29	28	29
Medical Technology patient caret	59	60	87	107
Personal Care	240	263	285	306
Rest categories	4	4	5	4
Total OTC	**323**	**340**	**335**	**339**

SOURCE: EFEX

4.6 EXTERNAL TRADE

Imports of the pharmaceutical sector amounted to €4.5 bil. in 2021, decreased by 4.5%, after an increase by 33.2% in 2020, while the sector's exports stabilized close to €2.9 bil., resulting in a deficit of €1.6 bil.

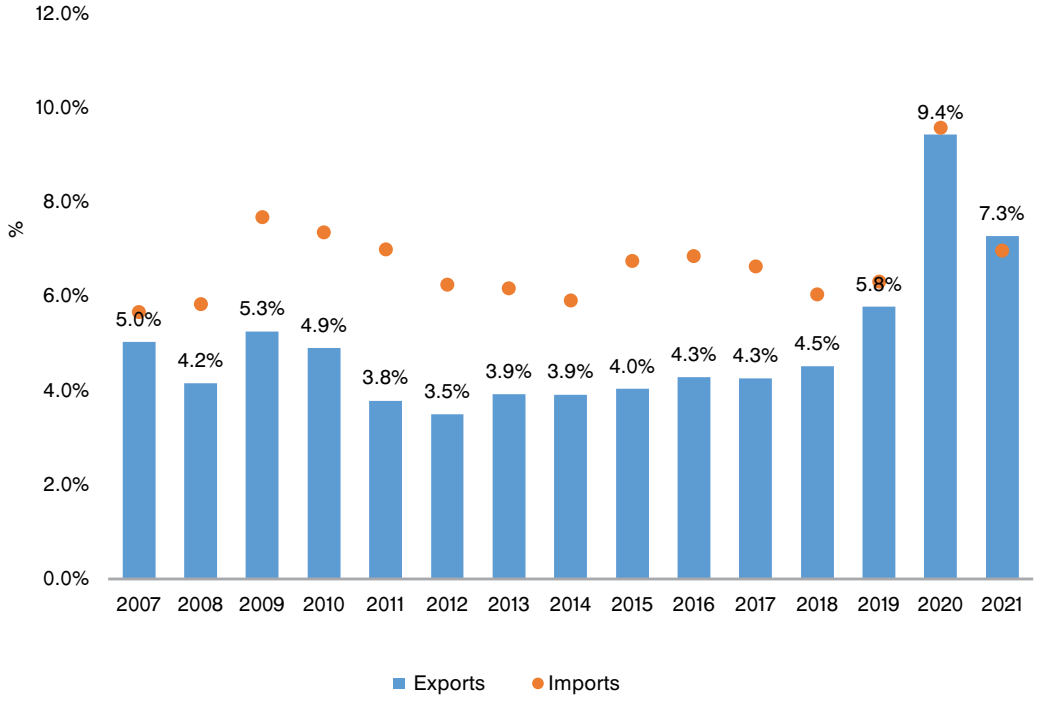
Figure 59: Evolution of pharmaceutical trade balance (mil.€)



SOURCE: Eurostat International trade, EU Trade Since 1988 By CPA, 2022, data processing IOBE

The exports of pharmaceutical products in relation to the total Greek exports, correspond to 7.3%% in 2021, remaining higher than before the pandemic. Respectively, imports account for 7.0% of total imports of the country in 2021, compared to 9.6% in 2020.

Figure 60: Share of pharmaceutical exports-imports (% of total exports-imports)-Greece



SOURCE: Eurostat International trade, EU Trade Since 1988 By CPA, 2022, data processing IOBE

France remains the first destination country for Greek pharmaceutical exports in 2021, with a share of 29.7%, despite last year's drop of 7.9%, followed by Germany with a share of 11.8%, registering an increase of 18.3 %. The UK and Cyprus follow with shares of 5.6% and 4.8%, while in the top 10 exports decreased in 2021 compared to 2019 in the UK and Spain.

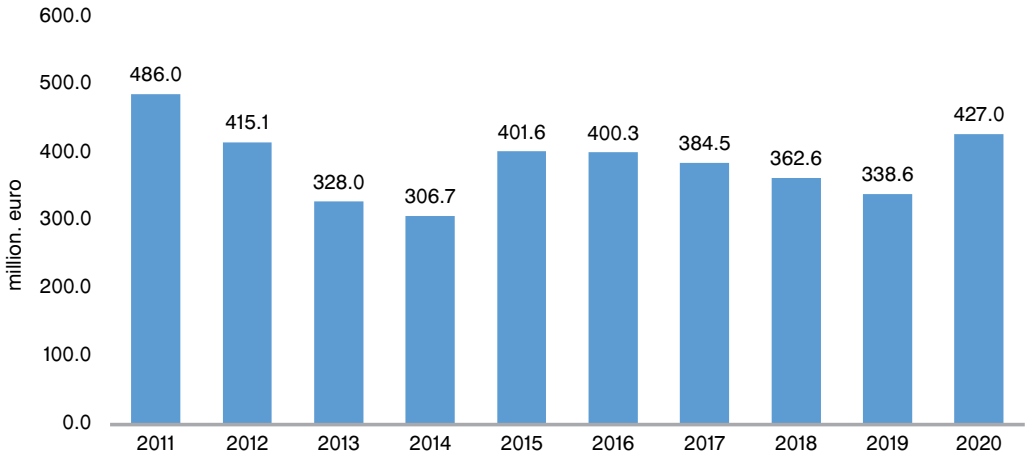
Table 3: Exports of medicines by country

Country	Exports 2021	Share 2021	% change (2021 vs 2020)	% change (2021 vs 2019)
France	861,340,987	29.7%	-7.9%	113.0%
Germany	343,527,170	11.8%	18.3%	14.3%
United Kingdom	163,761,360	5.6%	-14.0%	-10.2%
Cyprus	140,741,908	4.8%	14.1%	20.6%
Japan	121,734,948	4.2%	-47.9%	2067.7%
Austria	110,732,017	3.8%	-8.4%	22.6%
Italy	102,856,773	3.5%	7.8%	1.6%
Netherlands	102,515,056	3.5%	32.6%	72.7%
South Korea	94660,337	3.3%	18.9%	48.8%
Spain	79,773,879	2.7%	-36.2%	-16.2%

SOURCE: Eurostat, International trade, EU Trade Since 1988 By CPA, 2022, data processing IOBE

Part of the exports are parallel exports, which are recorded by EOF (National Organization for Medicines) based on sales declared by pharmaceutical companies. Parallel exports increased in 2020 to €427 million, compared to €338.6 million in 2019.

Figure 61: Parallel exports (in values) 2011-2020



SOURCE: EOF, 2022

4.7 PRICING OF PHARMACEUTICALS

According to Law 4638/2019 (Gazette 181 A '/ 18.11.2019) and MD 4274 B'/22.11.2019):

Table 4: Pricing system

Pricing (on-patent)	First pricing: • Average of 2 lowest different Eurozone prices • The product should be priced in at least 3 EU member states * The same MD about the status of biological, bio-similars, hybrid and biotech medicines
	Re-pricing Average of 2 lowest different Eurozone prices. • **Increase of the price:** no increase for the first pricing • If the price is higher than the average of the 2 lowest Eurozone prices: **Price Reduction** on each re-pricing up to 7% on the price of the preceding price list with a lower limit of the average of the 2 lowest different price in Eurozone. If with the new price, there is daily treatment cost (DTC). <0.20 € then the price of the product is reduced up to this limit. • Medicines with DTC ≤ 0.20 € are not re-priced
Pricing (off-patent)	First pricing: Average of 2 lowest different Eurozone prices Re-pricing: Average of 2 lowest different Eurozone prices the price in each case cannot be lower than daily treatment cost (DTC) (0.20€) • **Increase of the price:** no increase for the first re-pricing • If the price is higher than the average of the 2 lowest Eurozone prices: **Price Reduction** on each re-pricing up to 7% on the price of the preceding price bulletin with a lower limit of the average of the 2 lowest different price in Eurozone. If with the new price, there is daily treatment cost (DTC). <0.20 € then the price of the product is reduced up to this limit. • Medicines with DTC ≤ 0.20 € are not re-priced
Pricing (Generics)	65% of off-patent Re-pricing: • **Increase of the price**: no increase for the first re-pricing • If the price is higher than the average of the 2 lowest Eurozone prices or 65% of the off-patent price: **Price Reduction** on each re-pricing up to 7% on the price of the preceding price bulletin with a lower limit of the average of the 2 lowest different price in Eurozone. If with the new price, there is daily treatment cost (DTC). <0.20 € then the price of the product is reduced up to this limit. • Medicines with DTC ≤ 0.20 € are not re-priced
Re-pricing	1 time every year (December)

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 (Table 6).

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: a) 35% on the wholesale price for prescription non-reimbursed medicinal products b) for reimbursed prescription products see Table 6 and for non-prescription products up to 30% (Table 6)

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%,

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. 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 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 reimbursed by the social security funds profit margins and the price structure are set as follows:

Table 5: Mark-up in the pharmaceutical supply chain

	Reimbursed Products up to 200€	Reimbursed Products > 200.01€	Negative list products
Wholesalers (over ex-factory)	4.9%	1.5%	5.4%
Pharmacies	(Table 6)	(Table 6)	35%

SOURCE: M.D. (4274/22.11.2019)

Table 6: 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%

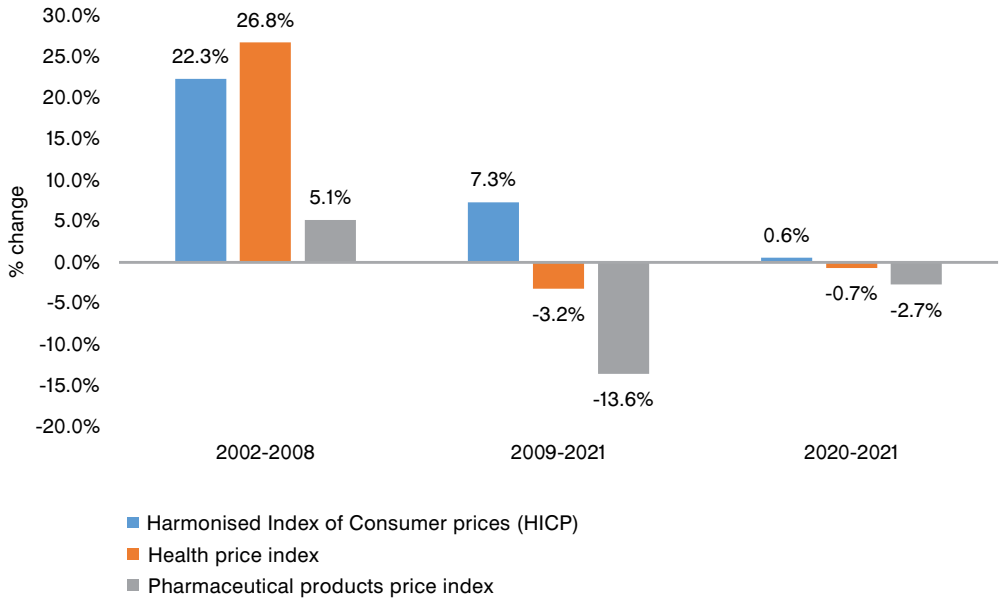
Wholesale price (€)	Percentage mark-up pharmacies
900.01 - 1000	5.50%
1000.01 - 1250	5.00%
1250.01 - 1500	4.25%
1500.01 - 1750	3.75%
1750.01 - 2000	3.25%
2000.01 - 2250	3.00%
2250.01 - 2500	2.75%
2500.01 - 2750	2.50%
2750.01 - 3000	2.25%
>3000	2.00%

SOURCE: M.D. (4274/22.11.2019)

Additionally, these mark-up margins mentioned above 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.

Between 2002 and 2008, prices increased by 5.1% presenting the lowest increase between health index (+26.8%) and the general price index (22.3%). From 2009 to 2019 the pharmaceutical price index reduced by 13.6%, the health price index by 3.2%, while a decrease is also recorded in 2021.

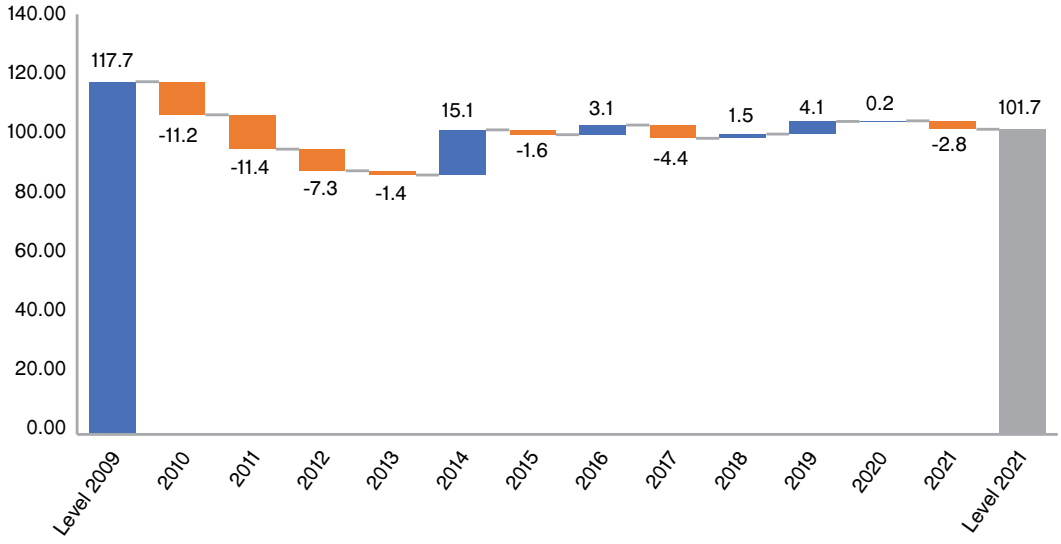
Figure 62: Annual change (%) of HCIP by category (2015=100)



SOURCE: Eurostat, Harmonised Indices of Consumer Prices (HICP), 2022 data processing IOBE

On an annual basis, the pharmaceutical price index recorded continuous declines in the period 2010-2013, while increased in 2014, 2016 and 2019-2020, however, these increases did not compensate the significant decreases in the first period, resulting in the decrease of the index by 17 points lower between 2021 and 2009.

Figure 63: Annual change (%) of HCIP by category (2015=100)



SOURCE: Eurostat, Harmonised Indices of Consumer Prices (HICP), 2022 data processing IOBE

4.8 HEALTH TECHNOLOGY ASSESSMENT (HTA)

The MAH (Holder of the Marketing Authorization) files an application to the HTA Committee for evaluation of the medicine, accompanied by a full dossier including all information and documentation. The Committee carries out a formal check of the dossier and informs the MAH of any deficiencies. If the dossier is incomplete, the MAH has 60 days to deposit the data otherwise required, the application will be rejected.

After the submission of the full dossier, a rapporteur and external evaluators are appointed who receive the dossier and draw up the relevant assessment reports. It is noted that the HTA Committee may, by unanimous and specifically reasoned decision, not appoint external evaluators or designate only one. The final proposal is then drafted, which is communicated to the members of the Evaluation Committee. Here is the evaluation of the suggestion. If the outcome of the evaluation is positive, the dossier shall be referred to the Negotiation Committee. The Negotiation Committee will hold a meeting with the MAH, assess the financial impact and suggest to the Evaluation Committee the compensation fee.

Then follows the opinion of the Negotiation Committee, which is forwarded to the Evaluation Committee and then to the Minister of Health. The decision of the Minister of Health shall be issued within 180 days of the filing of the application. Following the adoption of the decision of the Minister of Health, a summary of the opinions of the Evaluation Committee, which include at least their rationale, is published on the EOF's web site, after deletion of information regarding commercial confidentiality and personal data.

The Hellenic Association of Pharmaceutical Companies (SFEE) collects and records data related to State's outstanding debts of its member companies (on a voluntary basis). Below an overview of total receipts, sales invoices and debts until 31.12.2021 only for the pharmaceutical industry are presented.

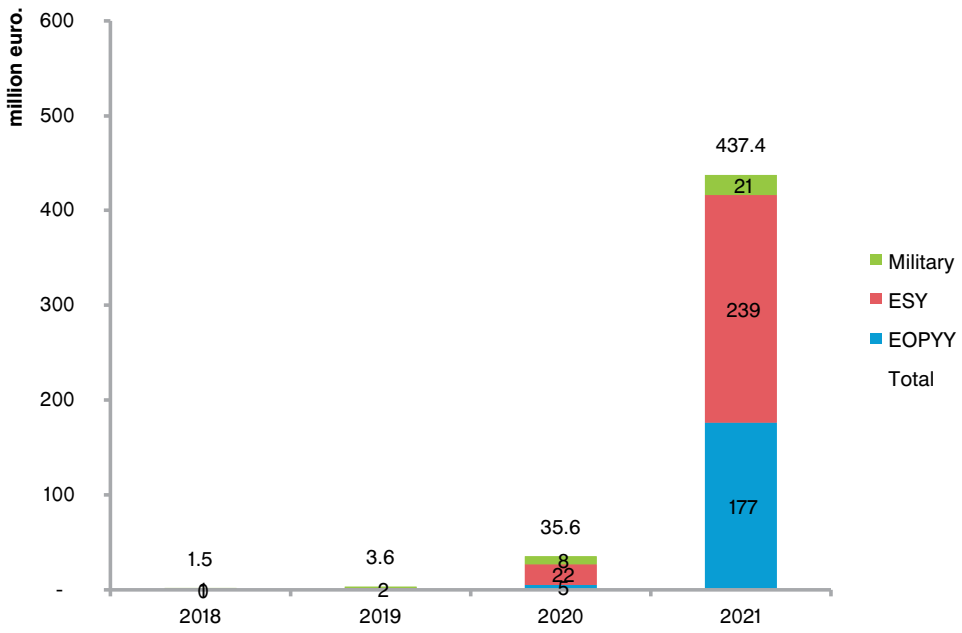
Data for outstanding debts from ESY hospitals, EOPYY, and Military hospitals also constitute the largest part of health expenditure.

Specifically, findings show that:

The amount of government outstanding debts to SFEE member companies until 31.12.2021 amounted to €478.1 mil., €182.3 mil. concerns EOPYY and €295.8 mil. concerns ESY while respectively until December 2020 amounted to 686.8 mil., €353.6 mil. concerns EOPYY and €333.5 mil concerns ESY.

More generally, there is a relatively stable repayment of the outstanding debts of the State to pharmaceutical companies. As, pharmaceutical companies are significantly six months 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 64: State debts evolution towards SfEE member companies' until per year (€ mil.)



SOURCE: SFEE

6.1 SYSTEM OF HEALTH ACCOUNTS (SHA)

In 2012, the Hellenic Statistical Authority (ELSTAT.) 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 (ELSTAT.) 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.

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
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 (e.g. 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.

6.2 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 citizens 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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