THE PHARMACEUTICAL MARKET IN GREECE

FACTS & FIGURES 2022

FOUNDATION FOR ECONOMIC & INDUSTRIAL RESEARCH

ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

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List of Figures

List of Tables

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"THE PHARMACEUTICAL MARKET IN GREECE: FACTS & FIGURES 2022"

It is with great pleasure to preface the renewed annual edition 'The Pharmaceutical Market in Greece: Facts & Figures 2022', prepared by the research staff of IOBE in collaboration with SFEE.

This report intends to provide a 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 includes all data available until the end of 2022, to present an updated profile of the pharmaceutical market and the main changes that occurred.

This year's edition takes place in a new environment of challenges, with the Greek economy further tested by strong inflation pressure caused by Russia's invasion of Ukraine. The pandemic crisis has highlighted the importance of the development and access to new innovative treatments and vaccines to address global health threats, suitable financing of health systems, cooperation between the pharmaceutical industry and governments, as well as evidence-based pharmaceutical policy. At the same time, it demonstrates the immediate need to create and support 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

In the **economic environment**, the Greek as well as the European economy were tested in the last three years, both by the pandemic that caused a significant reduction in economic activity, and by the energy crisis caused by Russia's invasion of Ukraine, creating strong inflationary pressures. The macroeconomic imbalance created, with an initial fall in income and then a strong recovery due to fiscal and monetary support measures, but also the increase in inflation, are factors of medium-term uncertainty.

The population health expenditure needs are affected by **demographic trends** and **developments**, such as the **negative natural balance** (births - deaths) where a decrease of 64.7 thousand people (2022) is observed and leads to a gradual decrease of the total population. While **high life expectancy** (80.2 years, close to the EU27 average of 80.1 years for 2021), combined with the **increase of the oldest population** (over 65 years) from 22.9% of the total population in 2022 to 33.5% in 2060, means that health and social insurance systems will be under greater pressure. For 2020, deaths from diseases of the circulatory system are responsible for 34.9%, while neoplasms are responsible for 23.5% of total deaths. In addition, the percentage of the population aged 16 and over with a chronic health problem is increasing from 2018 to 2022, reaching 24.9%. The percentage of the population over 65 with multiple chronic diseases in Greece reaches 40%, a percentage higher than the average of EU countries (36%).

Total health expenditure in Greece decreased by -22.1% in the period 2010-2022 (+10.9% in the Southern countries, +28.6% in the EU), and amounted to €16.7 bil. in 2021 (9.2% of GDP). **Public health expenditure decreased** by -29.2% (+6.4% in the Southern counties, +32.7% in the EU) over the same period, to €10.4 bil. in 2021 (5.7 % of GDP). The reduction in public health expenditure resulted in a shift to the private sector, with private health expenditure reaching 37.9% in 2021 (27.0% in the South, 18.9% in the EU).

Additionally, **pharmaceutical expenditure (outpatient and hospital)** amounted to €5.6 bil. in 2021, compared to €5.2 billion in 2020, while it is estimated at €6.2 bil. in 2022 **public expenditure** reached €2.6 bil. in 2021, at the same level as in 2020 and is estimated to have increased marginally in 2022 to €2.7 bil., while the **share of industry** in pharmaceutical expenditure increased in 2021 to €2.4 bil., compared to €2.0 billion in 2020. The estimation for 2022 is that the industry's contribution is higher around €500 mil., surpassing for the first time public pharmaceutical expenditure. Finally, patient contribution increased in 2021 to €662 mil., with an increase from 2020.

The continuous reduction in public pharmaceutical expenditure resulted in a remarkable increase in the returns and discounts of the pharmaceutical industry reaching 46% of total public pharmaceutical expenditure in 2021, from 6% in 2012.

Total public outpatient pharmaceutical expenditure (including estimated patients and pharmaceutical industry contribution) reached €4.2 bil. in 2021. Public expenditure (together with closed retail sub-

budgets) stood at €2.0 bil. in 2021, stable from 2020. Industry contribution (clawback, rebates, and closed sub-budget discounts) amounted to €1.5 bil. in 2021, compared to €1.4 bil, in 2020 and €272 mil. in 2012. The reduction in public outpatient expenditure over the period 2012-2021 by approximately 31% resulted in a significant increase in industry contributions over the same period by 458% and patient contribution by 59%.

For the period 2018-2021, of the 168 innovative medicines that received central authorization from the EMA, 90 medicines are available to the Greek patient, i.e. 54% of approved innovative medicines compared to 47% EU average In particular, 58% of the new medicines available in Greece, against the European average of 37%, are under a limited availability or reimbursement, mainly reflecting the medicines that are available through IFET and the Electronic Pre-Authorization System. Finally, regarding the time required from the date of approval of the drugs by the EMA to the date of their reimbursement by the health systems, Greece significantly lags behind the reimbursement time of a new treatment compared to the European average, as this is calculated equal to 674 days (against 517 days in the EU countries).

The pharmaceutical industry remains a pillar for investment in Greece with Research and Development (R&D) expenditure close to 8% of total R&D expenditure in Greece (2020) and 3,830 clinical studies independent of phase and stage conducted during the period 2002-2022 (2,250 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 €4.4 bil. and €2.6 bil., respectively in 2022 indicating a decline compared to 2020. Exports of pharmaceutical products accounted for 7.3% of total Greek exports in 2021.

The pharmaceutical industry sector is a driver of investment with R&D expenditure accounting for 8% of total R&D spending in Greece (2020), while in the period 2002-2022 3,830 clinical studies (all phases or stages) were conducted with 2,250 being completed. Additionally, for 2022 the domestic production of pharmaceutical products in value (ex-factory) amounted to €1.9 bil., with the added value reaching €1.5 bil. (6.4 % share in the manufacturing sector). The total employment in the pharmaceutical industry was 28.9 thousand people in 2022 with a clear upward trend in recent years. Finally, imports and exports of pharmaceutical products amounted in 2022 to €4.4 bil. and €2.6 bil., respectively, with a decrease compared to 2021. Exports of pharmaceutical products correspond to 4.7% of the total of Greek exports of all goods for 2022 with the main export destinations being Germany, France and the UK. Accordingly, imports make up about 4.7% of the country's total imports in 2022 compared to 6.9% in 2021.

ECONOMIC ENVIRONMENT

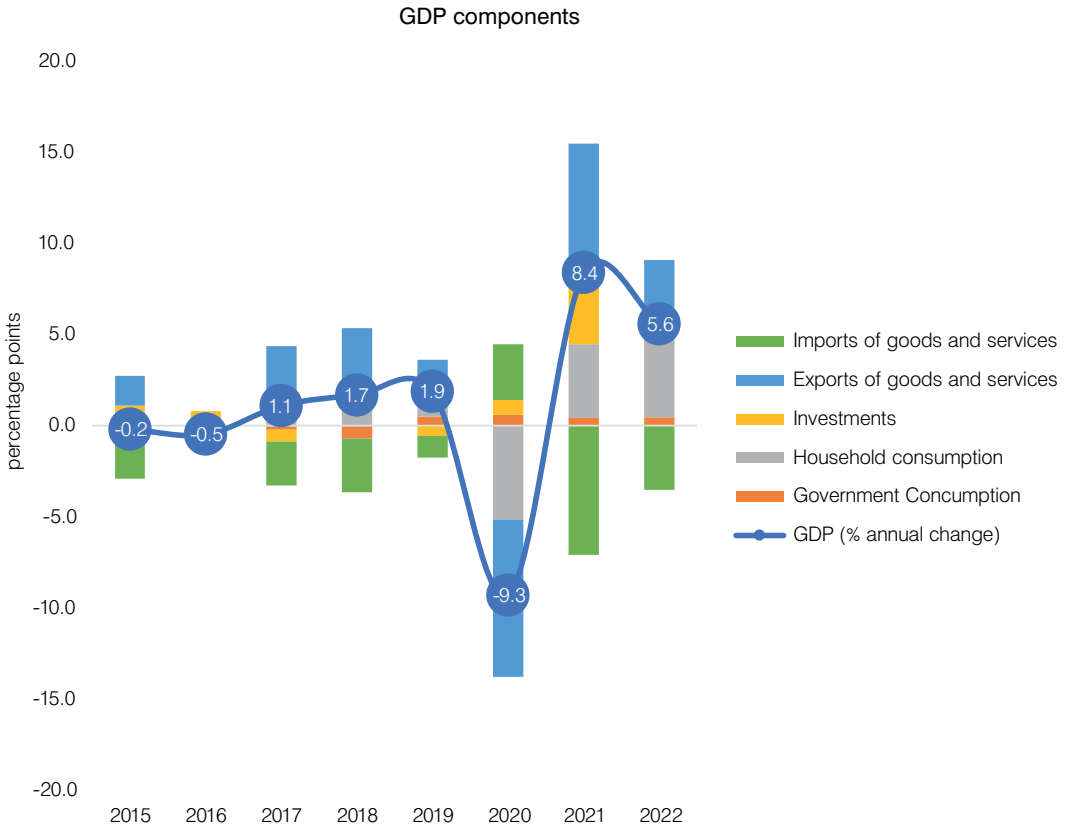
The Greek as well as the European economy have been tested in recent years, both by the pandemic which caused a significant reduction in the economic activity, and by the energy crisis caused by Russia's invasion of Ukraine, creating strong inflationary pressures. The macroeconomic imbalance, initially created from the fall in income and then a strong recovery due to fiscal and monetary support measures, but also the increase in inflation, are medium-term uncertainty factors.

Fiscal measures (expenditure increase, Recovery Fund) and monetary measures (ECB bond purchase program) are being phased out, as from 2024 the Eurozone countries will have to return to the new fiscal rules, after the escape clause will be deactivated, while the European Central Bank has proceeded from mid-2022 to continuous rise in interest rates, increasing borrowing cost for businesses and households. In these circumstances, a new pace of economic growth is sought, driven by investments, exports and reforms, to boost incomes and employment, while balancing inflation.

1.1 MACROECONOMIC ENVIRONMENT

Greece recorded GDP growth of 5.6% in 2022, following a strong recovery in 2021 of 8.4%, fully making up for the pandemic losses. The recovery of 2021-2022 was based on the increase in investments, private consumption, the increase in tourism receipts and spending, but also exports, mainly in 2021.

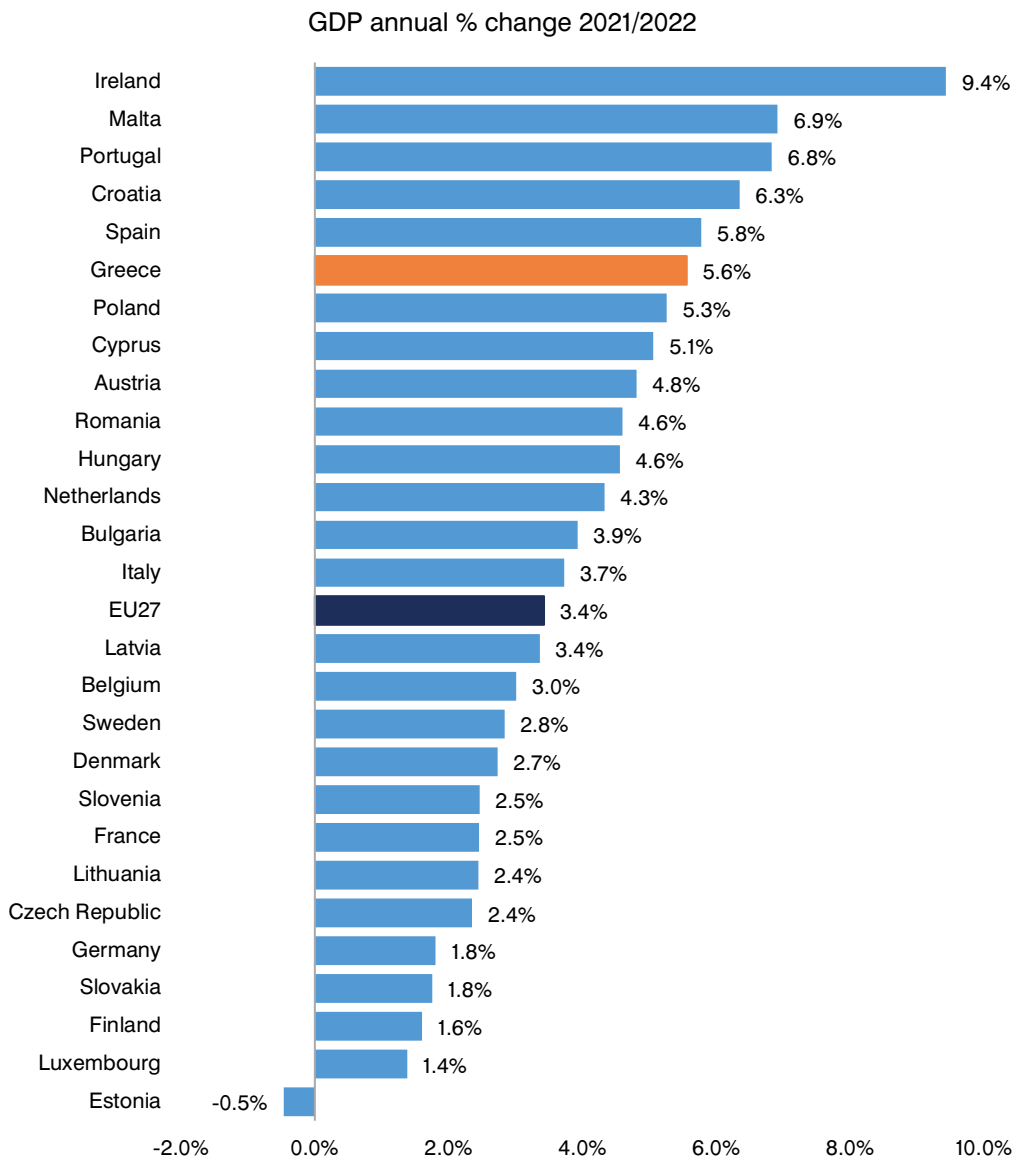
Figure 1: GDP components (€) and annual change (%) – Greece



SOURCE: Eurostat 2023, data processing IOBE

Greece recorded the sixth highest growth rate in 2022 among EU 27 countries, and well above average of 3.4%.

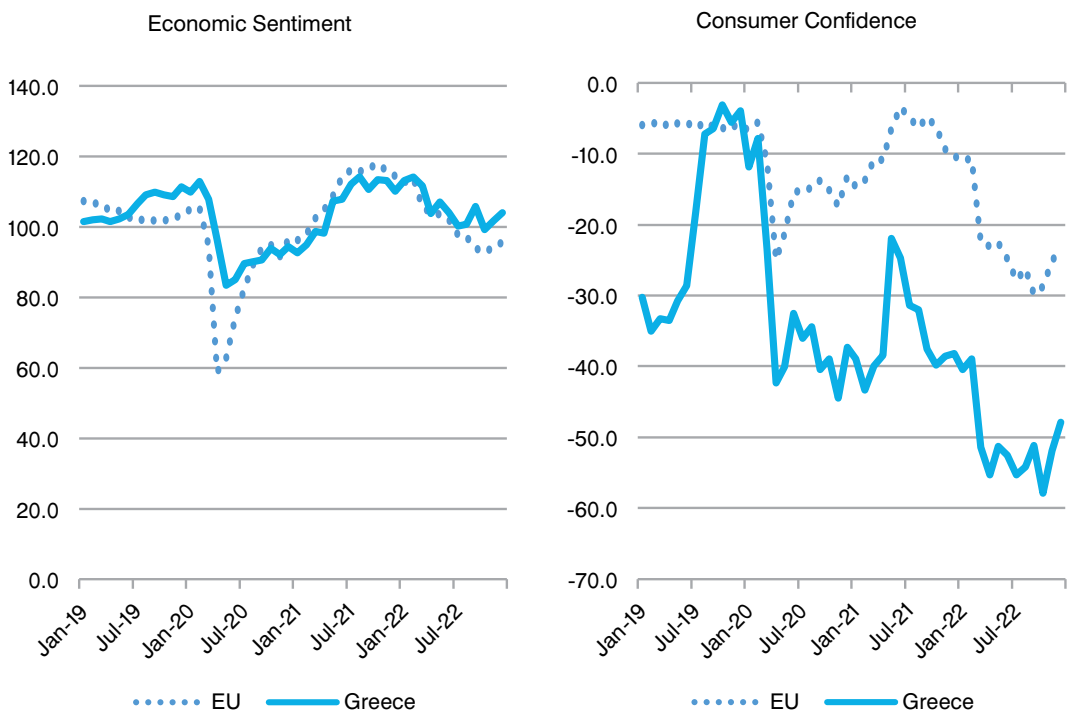
Figure 2: GDP evolution by country, 2022



SOURCE: Eurostat 2023.

The economic sentiment index moved higher in Greece versus the EU throughout 2022, while the strengthening continues into early 2023, a sign that businesses after the pandemic shock adjusted to the new conditions of high inflation. On the other hand, consumer confidence has diverged from the EU average since the beginning of the pandemic, with small periods of convergence, but maintaining its distance from the EU in 2022.

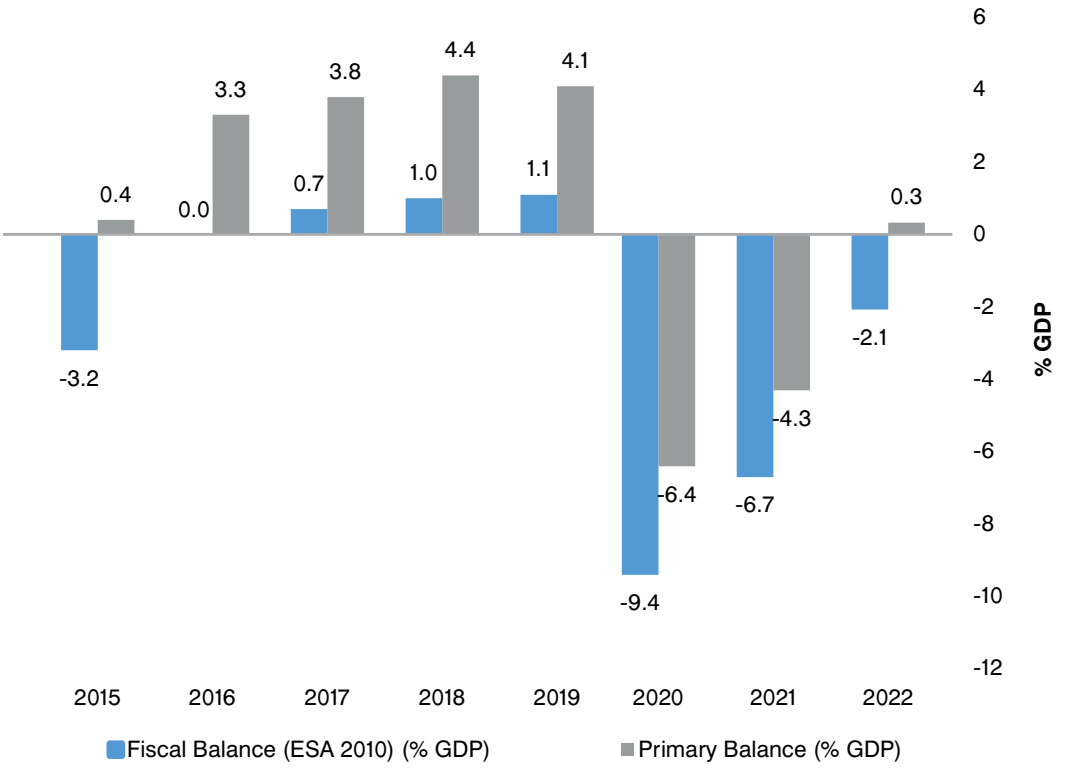
Figure 3: Economic Sentiment & Consumer Confidence



SOURCE: European Commission, DG ECFIN

The fiscal balance was corrected in 2022, following strong deficits in 2020 and 2021 due to measures to support the economy, bringing the deficit to 2.1% of GDP, from 6.7% in 2021. The primary balance returned to a positive percentage, at 0.3% of GDP, after the two years 2020-2021. This correction is due to an increase in nominal GDP and due to inflation, a gradual reduction in spending to support businesses and households and an increase in tax receipts, partly due to inflation.

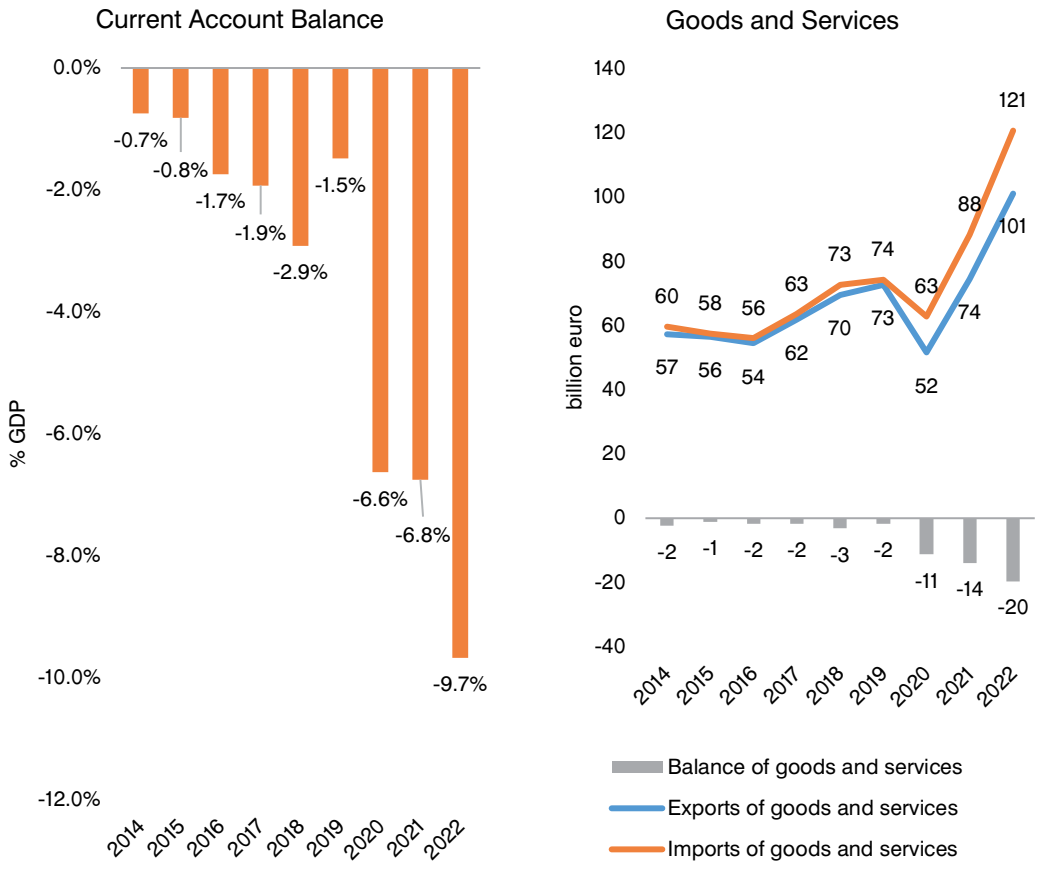
Figure 4: Fiscal Balance and Primary Balance



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.

A shrink of the current account deficit is recorded in 2022 to 9.7% of GDP, compared to 6.8% in 2021 and much lower levels in the period 2014-2019, rising borrowing needs of the economy. The balance of goods and services, which is also the largest part of the Current Account, recorded a deficit of €20 bil. in 2022, with increasing imports at €121 mil. and exports at €101 billion. The 1/3 of exports and imported goods concerns fuel, with a significant increase in their prices in 2022, while many other categories of goods also recorded a price increase.

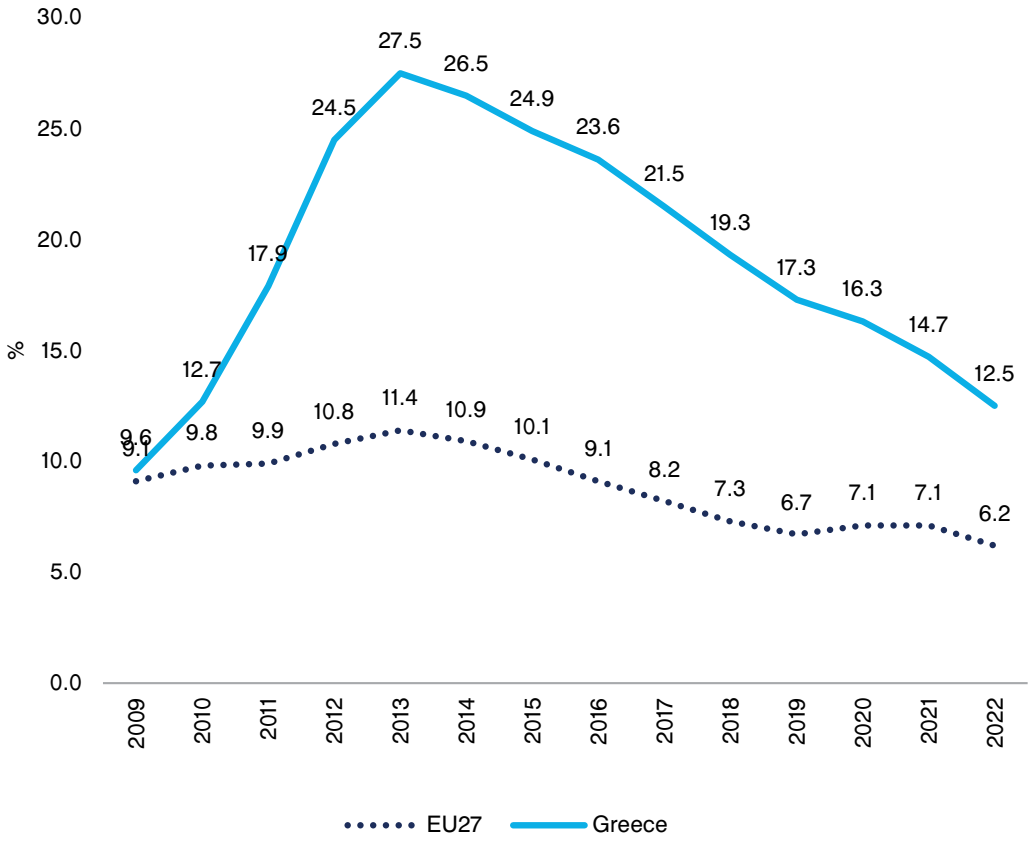
Figure 5: Current Account Balance



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).

The unemployment rate has gradually decreased since 2014, reaching 12.5% in 2022, compared to 6.2% in the EU27. This reduction is significant in a highly unstable macroeconomic environment, while employment increased by 210 thousand people.

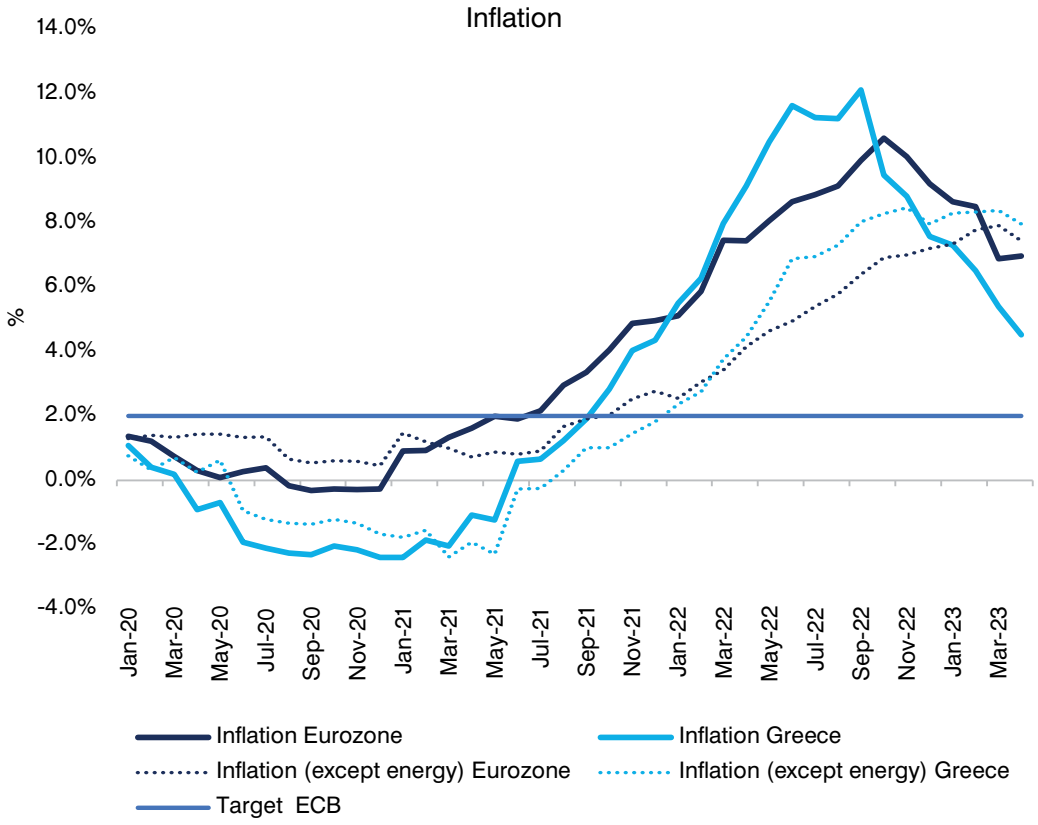
Figure 6: Unemployment rate Greece-EU27



SOURCE: Eurostat, 2023, data processing IOBE

Harmonized inflation in Greece is set at 9.3% in 2022, compared to 8.4% in the Eurozone average. The demand expanded due to support measures, the following energy crisis triggered a spiral of increase in many types of goods and services. After September 2022 and the gradual de-escalation of international fuel prices, a downward trend of inflation is recorded in Greece, continuing in 2023, stronger than the Eurozone, however non-fuel inflation remains strong, putting pressure on household purchasing power.

Figure 7: Inflation Greece-EZ

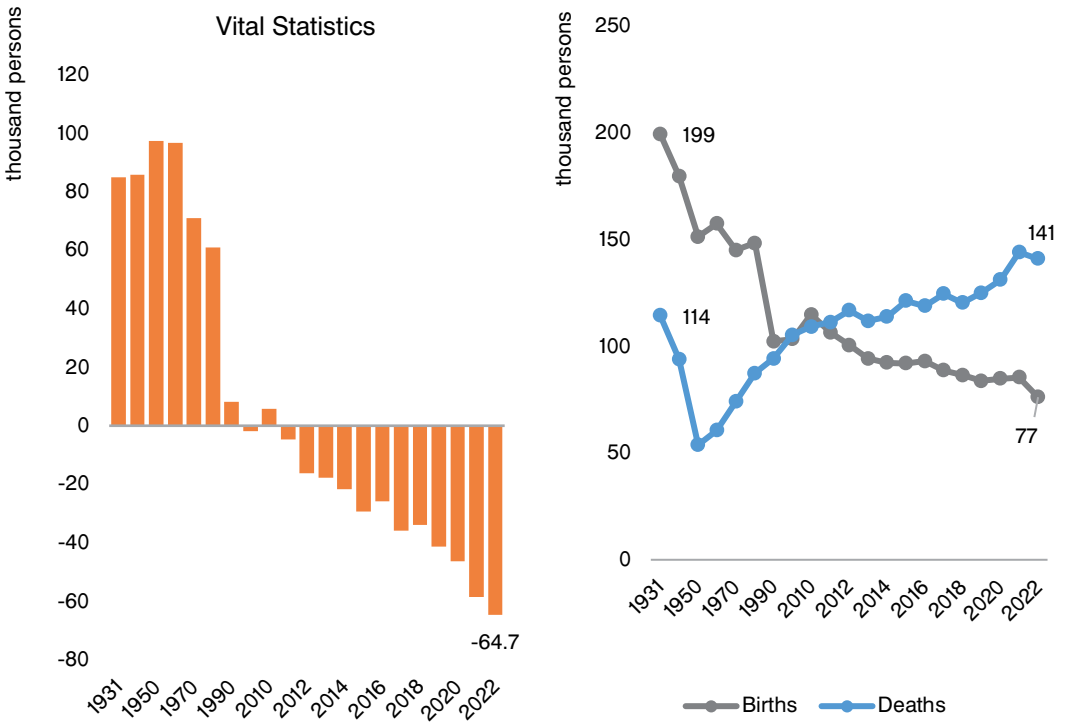


SOURCE: Eurostat, 2023, data processing IOBE.

2.1 NATURAL POPULATION CHANGE

The number of births in Greece amounted to 76,5 thousand in 2022 recording a decrease of 10.3% in comparison to the previous year, while compared to 10 years ago, births decreased by 23 thousand. The number of deaths also recorded a decrease of 2.2%, amounting to 140.8 thousand. As such, the natural population change (difference in births - deaths) result in an overall reduction of -64.3 thousand persons in 2022.

Figure 8: Natural population change (thousand persons)-Greece

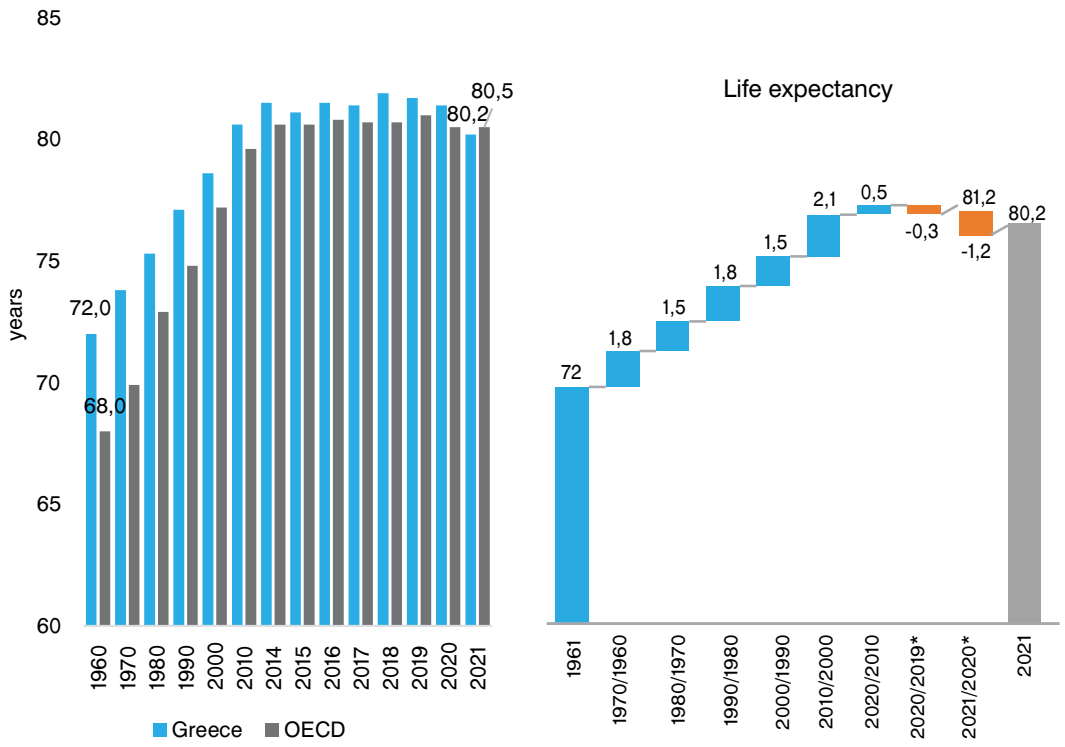


SOURCE: ELSTAT., 2023 *Natural population change (natural balance) is defined as the difference between births and deaths without taking into account net migration (immigrants – emigrants) ** The number of births does not include stillbirths, which in 2022 amounted to 446.

2.2 LIFE EXPECTANCY

The technological advances, improvement in the provision of healthcare services, contribution of R&D and introduction of new innovative medicines and therapies are some of the most important factors explaining the increase in life expectancy. Life expectancy in Greece has increased considerably by 8.2 years during 1960-2021 recording a higher life expectancy than the average of OECD countries for the same period. Every decade life expectancy in Greece extended by 1.5-2.0 years, while a negative change was recorded in 2020 and 2021, with Greeks "losing" 1.5 years of life expectancy.

Figure 9: Evolution of life expectancy at birth (years), Greece-OECD

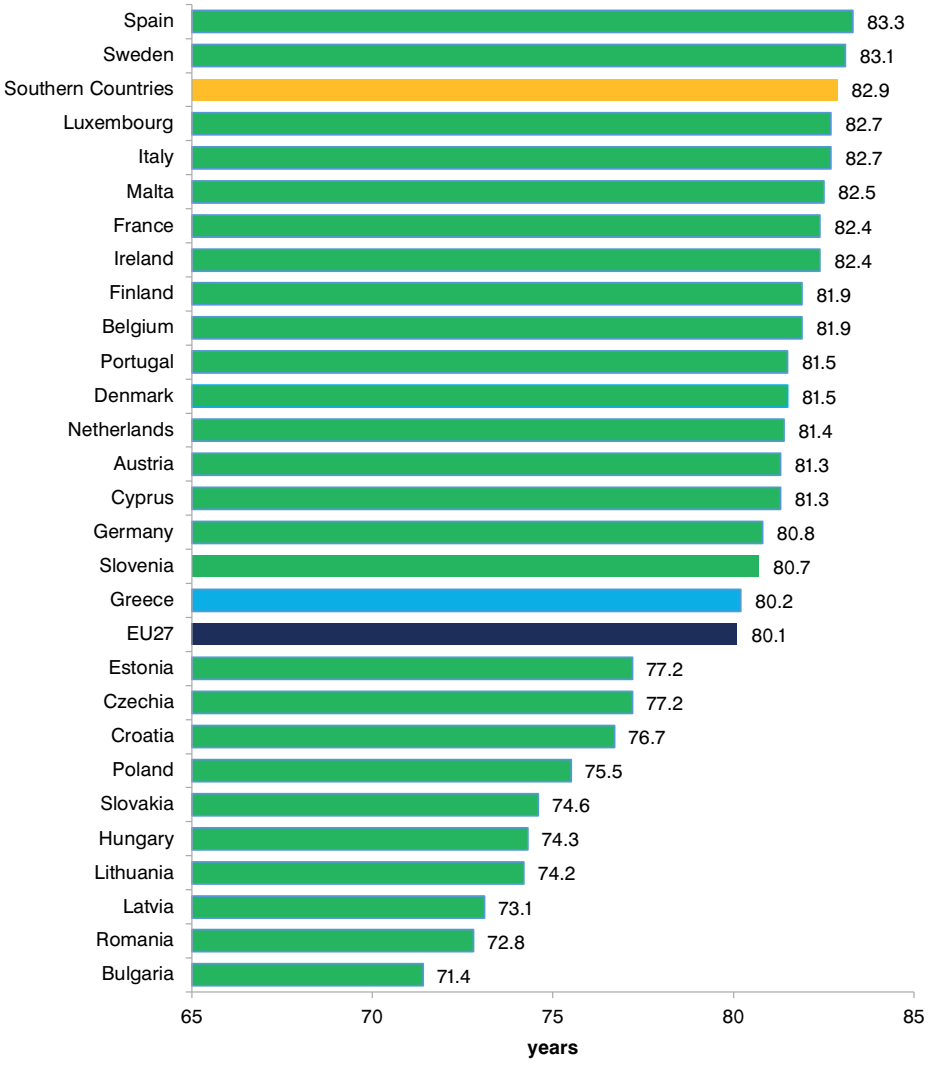


SOURCE: OECD, Health Statistics 2023

2.3 AGEING POPULATION

Life expectancy in Greece reached 80.2 years in 2021, like the EU27 average (80.1 years) and lower than in Southern countries (82.9 years). The highest life expectancy was recorded in Spain, Sweden and Italy.

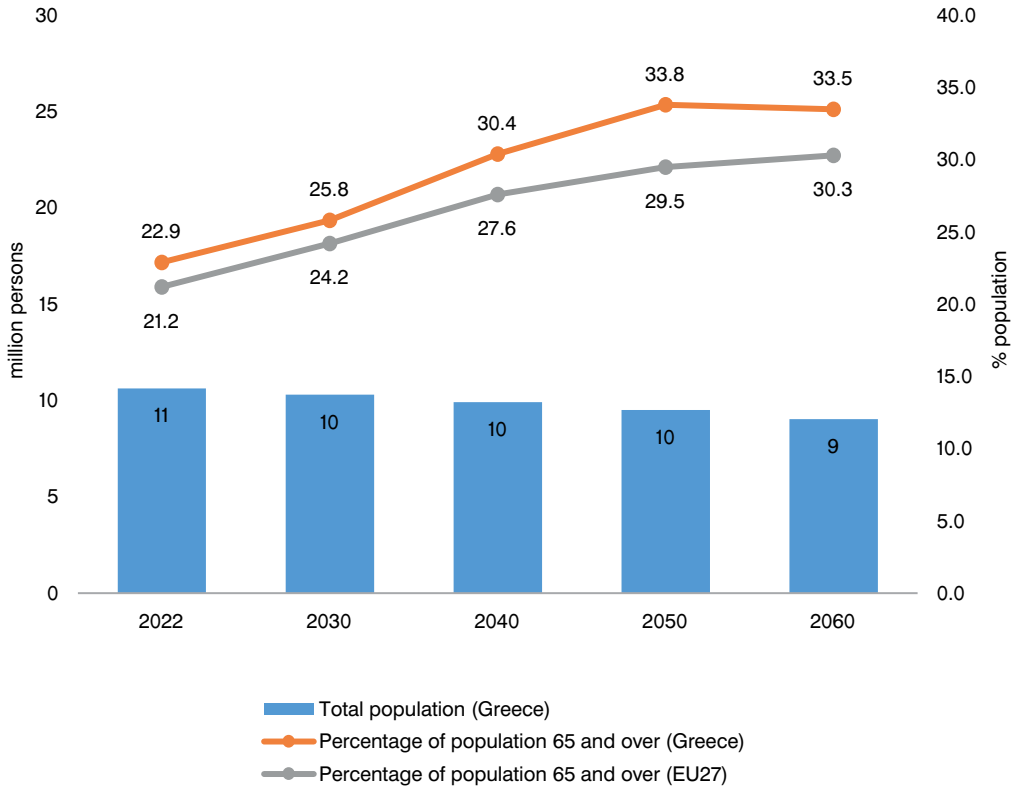
Figure 10: Life expectancy at birth (years) Greece-EU22-Southern countries (2021)



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 the 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 11: Population aged 65 and above (% total population) Greece-EU27

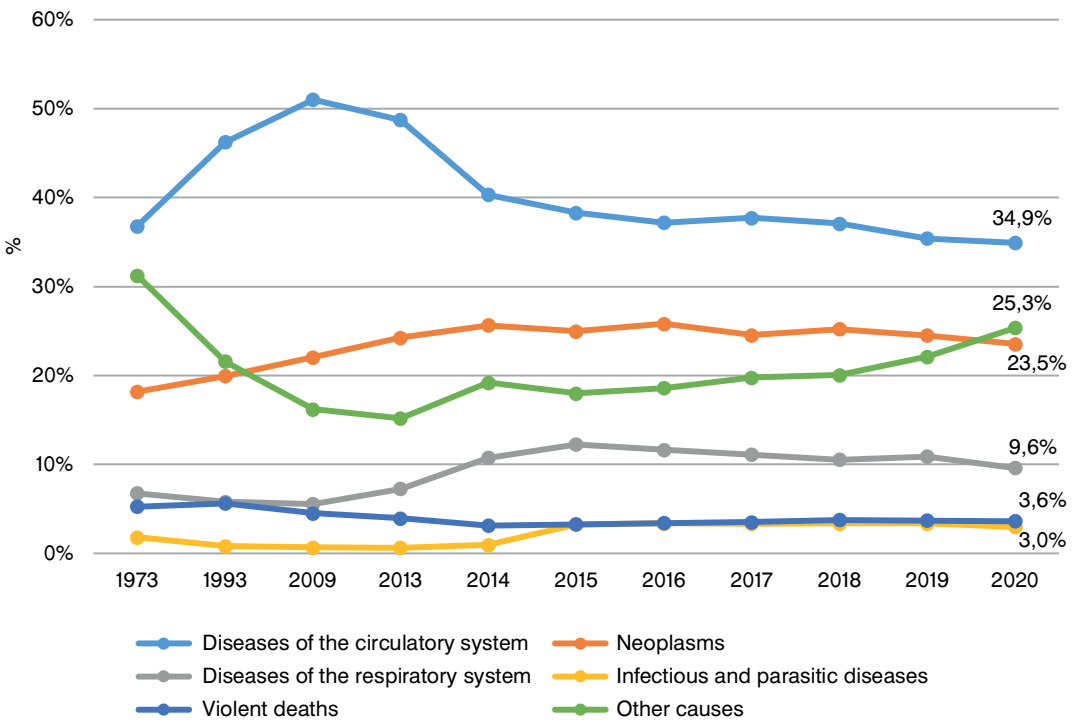


SOURCE: Eurostat, Population Projections, 2022, data processing IOBE *Not included the possible legalization of migration from 2015 onwards

2.4 CAUSES OF DEATH-CHRONIC DISEASES-PREVENTION

Over time, a significant increase in deaths due to circulatory system diseases is recorded, responsible for 34.9% of total deaths, despite the decline in recent years from 2017 onwards. Decrease in neoplasms is recorded, accounting for 23.5% of total deaths. Interestingly, the increase in the share of diseases of the respiratory system from 2009 until 2015, after a stabilization period.

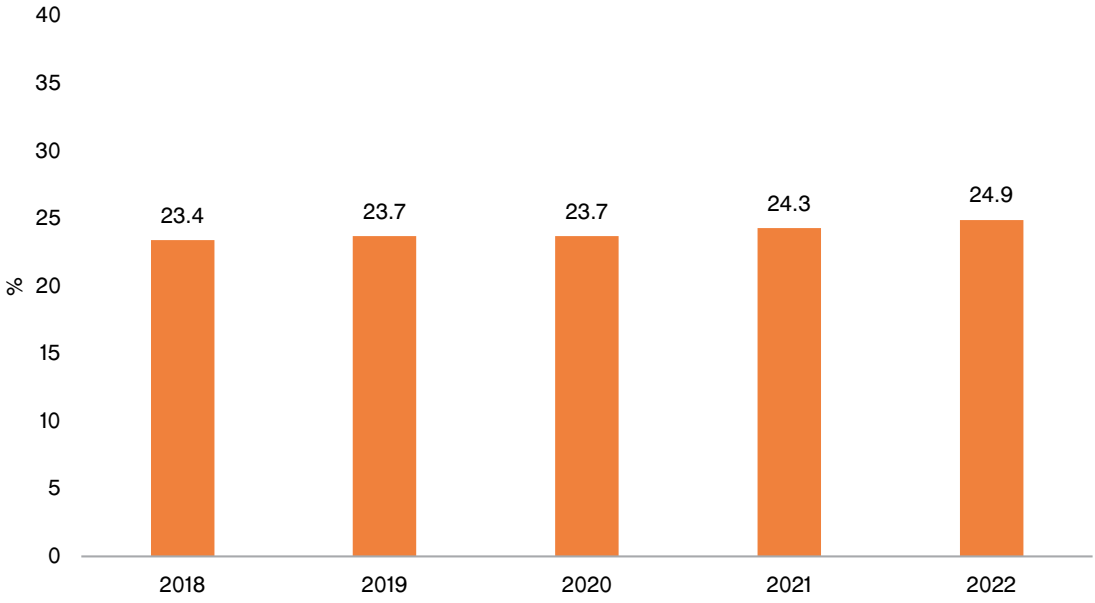
Figure 12: Causes of death (% of total deaths) – Greece (2020)



SOURCE: ELSTAT, 2023 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, nutritional deficiencies and immune disorders

According to ELSTAT survey results, the percentage of population aged 16 years and over suffering from a chronic illness or condition increased from 2018 to 2022 (24.9%). About 3 out of 10 women (27.0%) and 2 out of 10 men (22.6%) state a chronic illness or condition.

Figure 13: Percentage of population with chronic disease, aged 16 years and over, 2018-2022

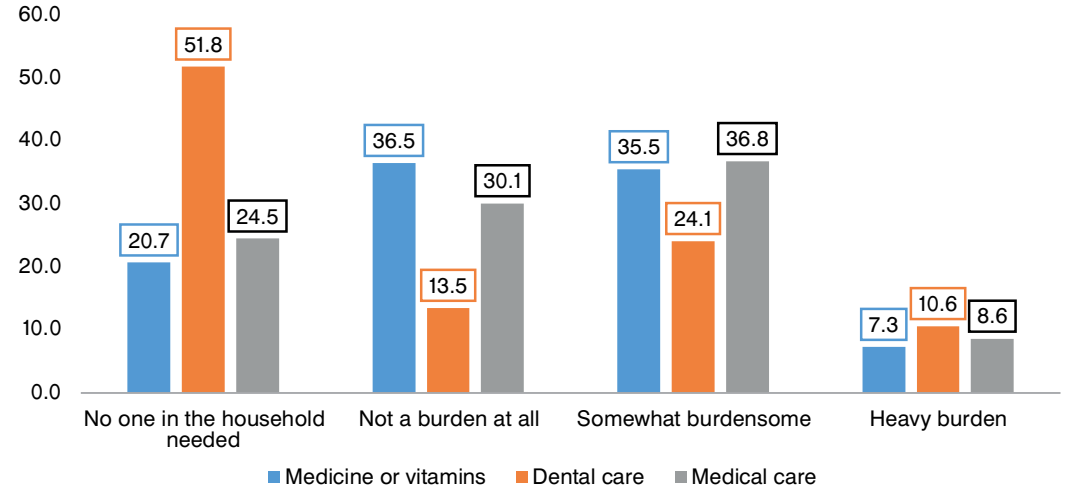


SOURCE: ELSTAT, 2023, Chronic illness or health problem means illnesses or health problems which have lasted, or are expected to last, for 6 months or more, with or without medication

The survey investigates whether health costs burdened households financially, during the last 12 months. The financial burden is considered separately for (a) provision of medical care (medical examinations, visits to doctors, hospitalizations, etc.), (b) provision of oral care (dental medical examinations or treatments, visits to dentists/orthodontists/orthodontists) and (c) purchase of medicines, herbs or vitamins (with or without a doctor's prescription, whether prescribed or not, excluding birth control pills and any other hormones used only for contraception).

More specifically, 8.6% of the population aged 16 and over, are financially burdened by the costs of providing medical care, 10.6% of the population aged 16 and over, are financially burdened by the costs of providing oral/dental care and 7.3% of the population aged 16 and over, are financially burdened by the costs of purchasing medicines or vitamins.

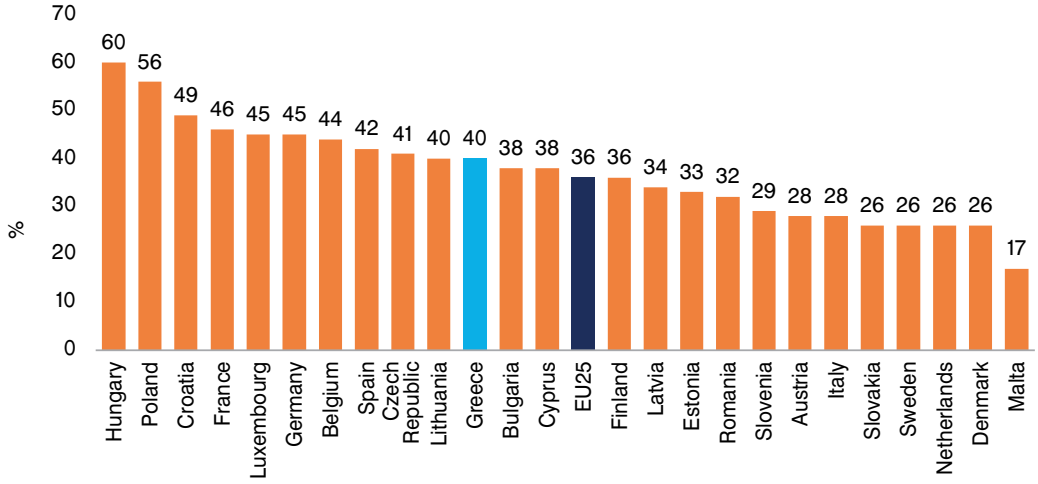
Figure 14: Financial burden of the household for medical care, dental care, medicine, or vitamins, 2022



SOURCE: ELSTAT, 2023

The percentage of the population over 65 with multiple chronic diseases reaches 40% and it is higher than the average of the EU25 countries (36%).

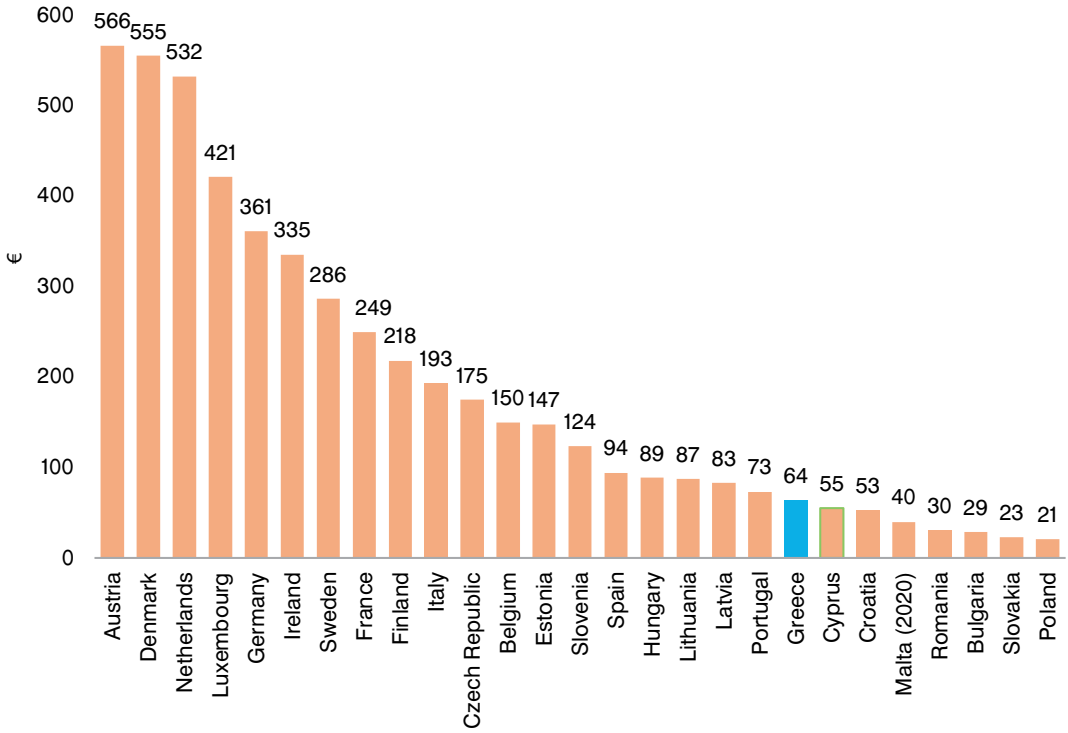
Figure 15: Percentage of population suffering from multiple chronic diseases, aged 65 years and over, (2021), EU25



SOURCE: Survey of Health, Ageing and Retirement in Europe * Note: EU average is unweighted. Chronic diseases include Alzheimer's disease, cancer, chronic kidney diseases, chronic lung diseases, diabetes, heart attack, hip fracture, Parkinson's disease, stroke, rheumatoid arthritis and osteoarthritis.

In 2021 the per capita spending on prevention in Greece reached €64 (from €27 in 2020), one of the lowest shares in EU, while the increase recorded in almost all countries it is partly also due to vaccination.

Figure 16: Prevention expenditure per capita, Greece-EU (2021)

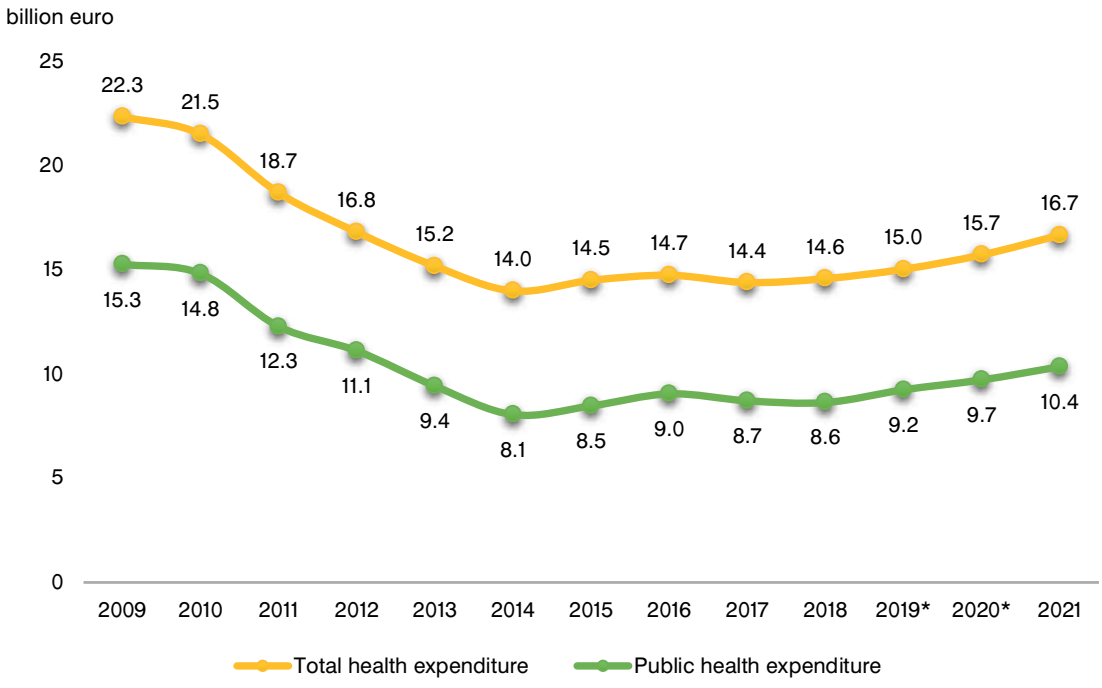


SOURCE: OECD, Health Statistics 2023

3.1 FUNDING ON HEALTH EXPENDITURE

In 2021, total health expenditure in Greece amounted to €16.7 bil., which was increased compared to the previous year, also due to the needs the pandemic. Public health expenditure reached €10.4 bil. increased by €633 million. compared to 2020 while private health expenditure increased by €312 million, to €6.3 billion. in 2021.

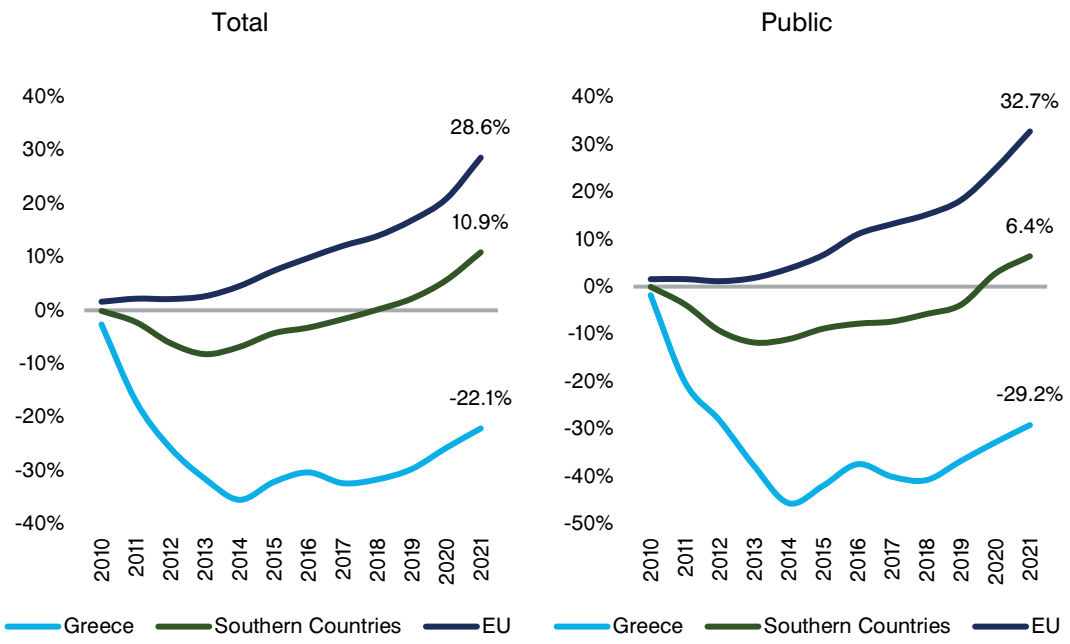
Figure 17: Total and public health expenditure (bil.€)



SOURCE: System of Health Accounts (SHA) 2021, ELSTAT, 2023, data processing IOBE*. *Revised data

Specifically, the index of GDP cumulative change in total health expenditure in 2021 compared to 2009, showed an increase of 10.9% in Southern countries, while an increase of 28.6% was recorded in the EU and a decrease of -22.1% in Greece during the same period. Similarly, a cumulative increase of 6.4% was recorded in public health expenditure in Southern countries, while an increase of 32.7% was noted for EU. In Greece a decrease of 29.2% during the same period.

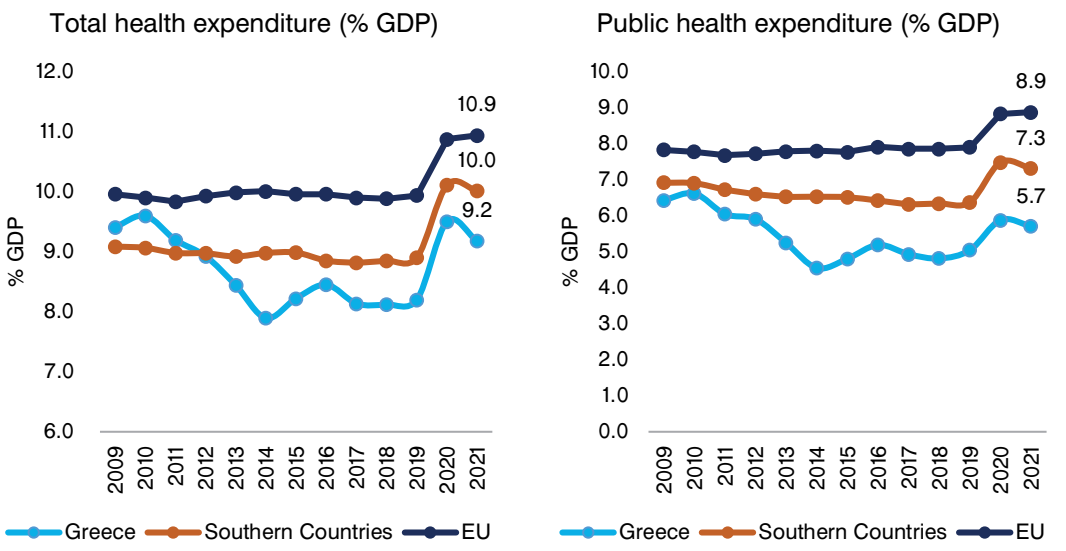
Figure 18: Index of cumulative change on health expenditure (%) Greece-EU-Southern countries



SOURCE: OECD Health Statistics, 2023, IOBE data processing Southern countries (Italy, Spain, Portugal). 2009 has been chosen as the comparison year and Percentage changes between 2009 and 2021 have been calculated at constant prices (€2015, OECD).

In 2021, the total health expenditure in the EU27 corresponds to 10.9% of GDP and to 10% in the Southern Countries, while Greece records 9.2% of GDP. The percentages increased in the period 2020-2021 compared to the previous period, due to the increased needs created by the pandemic in the health systems, and the relative drop in economic activity. In Greece, health expenditure is 1.6 units of GDP lower than the EU27 in the decade 2012-2021. Public funding for health expenditure in Greece reached 5.7% of GDP in 2021, slightly down compared to 2020 due to GDP growth. In the Southern Countries the corresponding percentage was 7.3% and in the EU27 at 8.9%

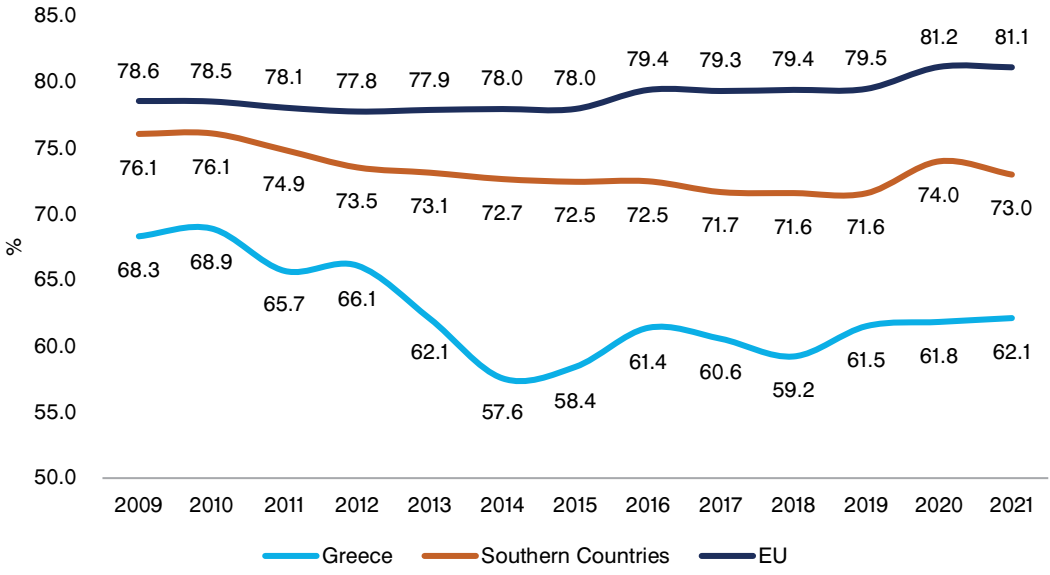
Figure 19: Total & Public health expenditure (% GDP) Greece-EU27-Southern countries



SOURCE: System of Health Accounts (SHA) 2021, ELSTAT., 2023, OECD Health Statistics, 2023, data processing IOBE. Southern countries (Italy, Spain, Portugal).

In 2021 public health expenditure accounts for 62.1% of total expenditure in health, remaining below the EU average and Southern countries. It is noted that the share of public expenditure in Southern countries and EU are by 10 and 20 units correspondingly higher compared to Greece.

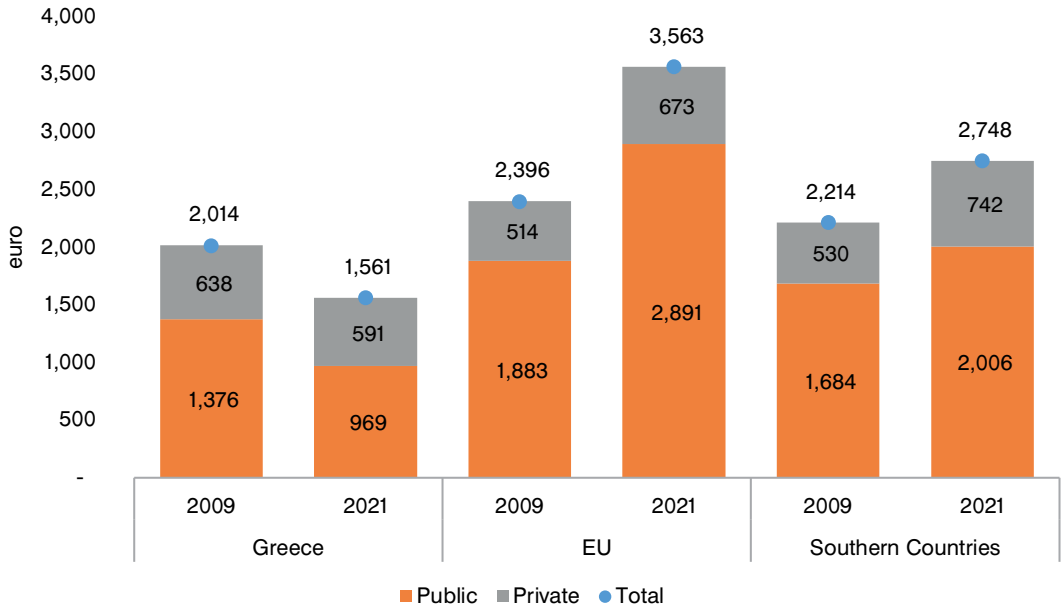
Figure 20: Public health expenditure (% of total expenditure) Greece-EU27-Southern countries



SOURCE: OECD Health Statistics, 2023, data processing IOBE. Southern countries (Italy, Spain, Portugal).

Total health expenditure per capita in Greece amounted to €1,561 in 2021 compared to €2.014 in 2009. It is calculated that 90% of the drop coming from the decline in public expenditure per capita in the same period. The per capita expenditure in the EU27 was €3,563, and Greece stands at 44% of the EU27 average and at 57% of the levels of the Southern countries. The increase in health expenditure per capita in the EU27 came by 86% from the increase in public expenditure and by 60% in the Southern Countries. Public health expenditure per capita amounted at €969 in Greece, 1/3 of EU27 levels.

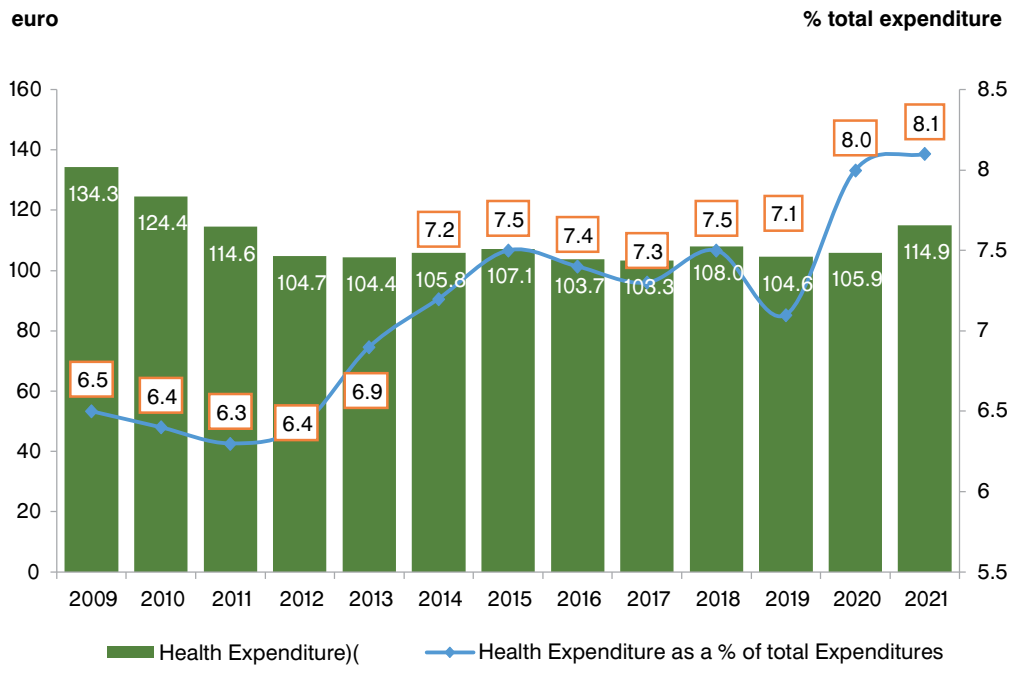
Figure 21: Total per capita health expenditure Greece-EU27-Southern countries



SOURCE: Eurostat,2023, OECD Health Statistics, 2023, data processing IOBE Southern countries (Italy, Spain, Portugal).

Health spending accounts for 8.1% of total household spending through market transactions for 2021, compared to 6.5% in 2009. Although the average monthly expenditure per household on health in 2021 showed a decrease of -14.4% in absolute terms compared to 2009 (€114.9 in 2021 against €134.3 in 2009), the percentage of these expenses is higher than in 2009, showing the reduced purchasing power of households, the increased participation of patients for health costs and the inelasticity of the expenditure for the specific categories.

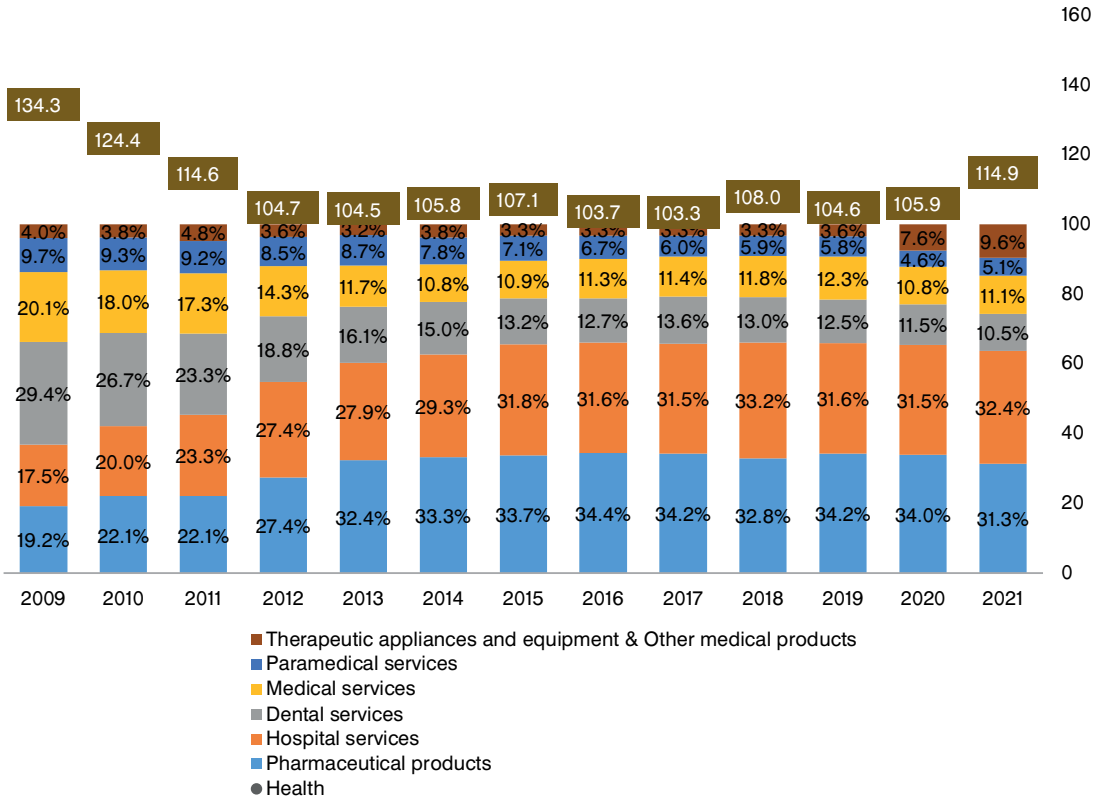
Figure 22: Health expenditure of households (€) per month-Greece



SOURCE: ELSTAT 2022, 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.

Specifically, from €114.9 monthly health expenditure per household in 2021, 31.3% refers to pharmaceuticals and 32.4% to hospital services, 10.5% to dental services and 11.1% to other medical services.

Figure 23: Breakdown of household health expenditure (%) per month - Greece

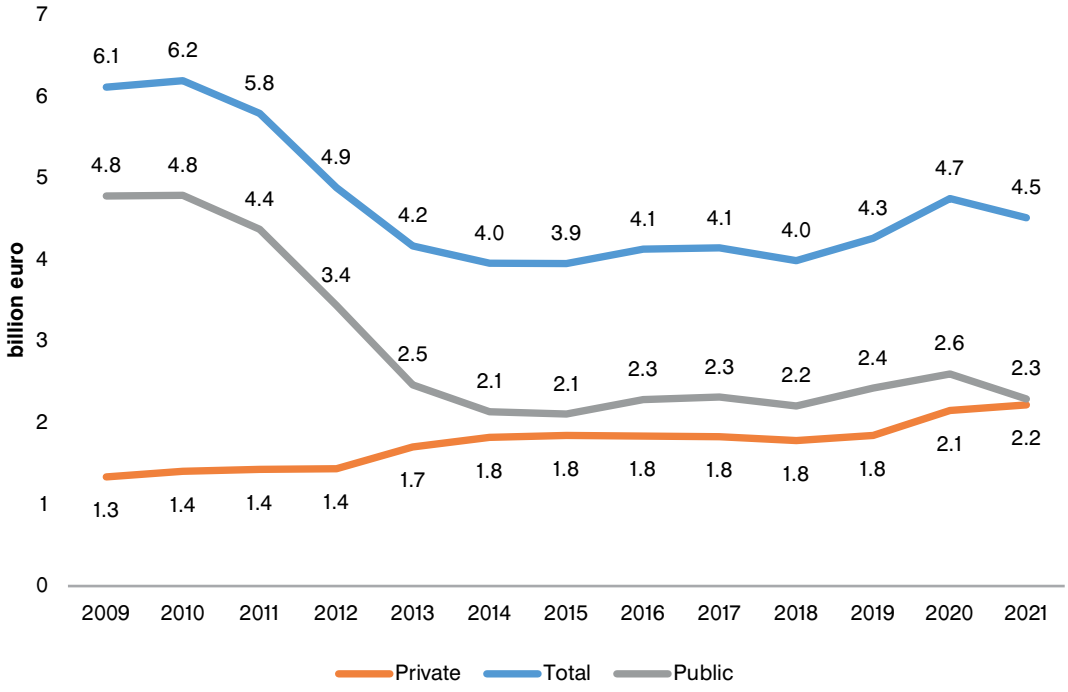


SOURCE: ELSTAT, 2022, data processing IOBE

3.2 PHARMACEUTICAL EXPENDITURE

Total expenditure for pharmaceuticals and other medical non-durable goods accounted for €4.5 bil. in 2021, recording a decrease of -26.2% compared to 2009. Correspondingly, public expenditure for pharmaceuticals and other medical non-durable goods from €4.8 bil. in 2009 amounted to 2.3 bil. in 2021, recording a further decline of 52.1%, while private expenditure for pharmaceuticals and other medical non-durable goods increased from €1.3 bil. in 2009 to €2.2 bil. 2021.

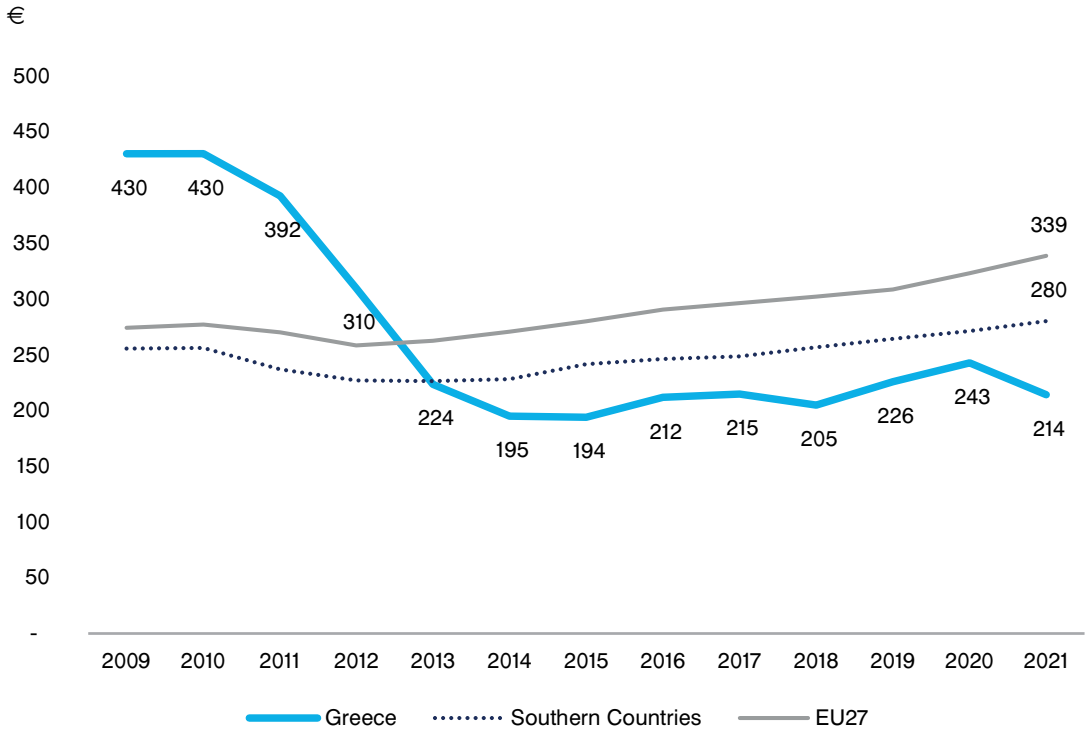
Figure 24: Total expenditure for pharmaceuticals and other medical non-durable goods (bil. €)-Greece



SOURCE: System of Health Accounts (SHA) 2021, ELSTAT, 2023, 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 was observed in public per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece since 2009 from €430 in 2009 to €214 in 2021, while after 2014 it has stabilized at lower levels than the EU27 and the Southern Countries. On the contrary the expenditure per capita in the EU27 was €339 in 2021 and €280 in the Southern Countries, following an increasing trend since 2012.

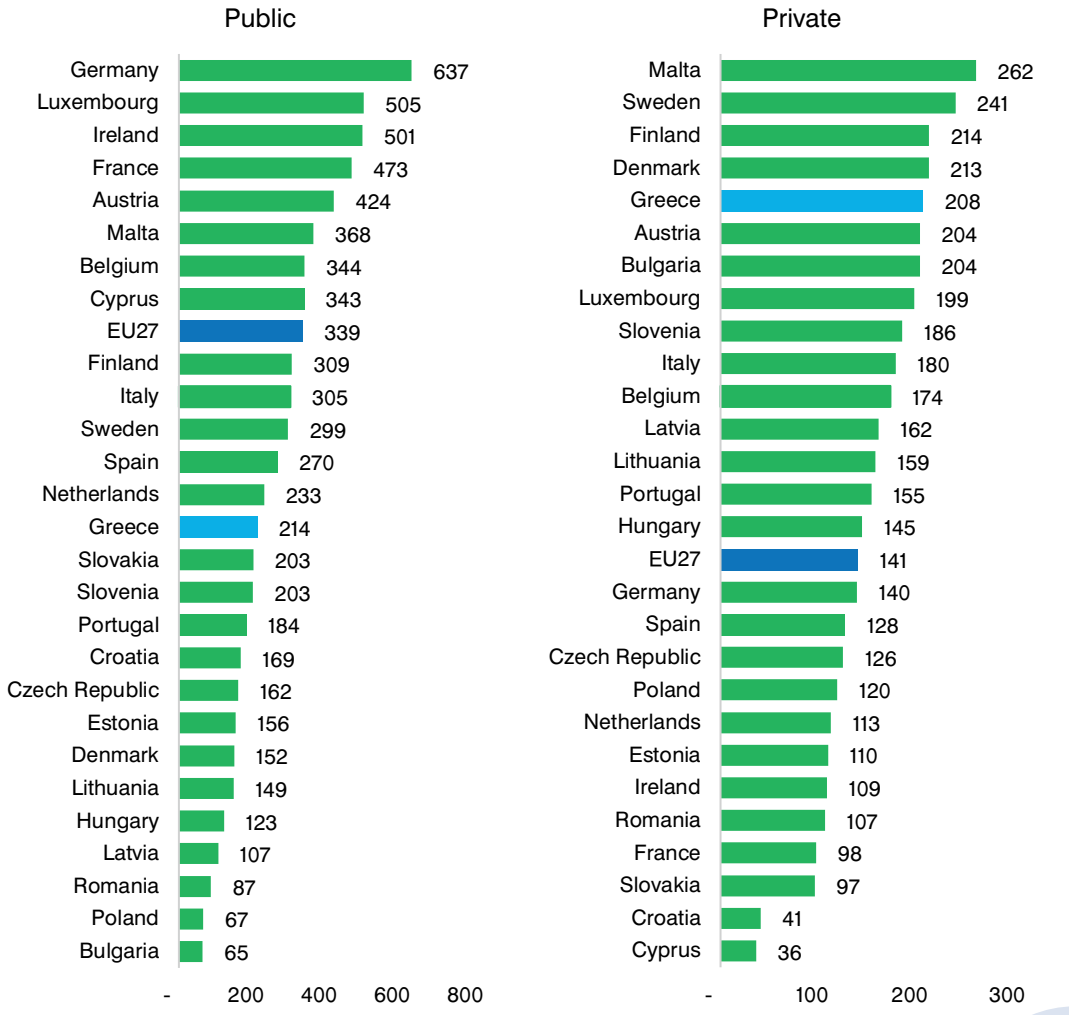
Figure 25: Public per capita expenditure for pharmaceuticals and other medical non-durable goods Greece-EU27-Southern countries (2009-2021)



SOURCE: Eurostat 2023, OECD Health Statistics, 2023, data processing IOBE. Southern countries (Italy, Spain, Portugal).

More specifically, the higher public per capita expenditure in 2021 for pharmaceuticals and other medical non-durable goods was recorded in Germany, Luxembourg and Ireland, while Greece (€214) is below the average of EU27 (€339). On the contrary, private per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece (€208) is higher than the average of EU27 (€141), ranking 5th among EU countries.

Figure 26: Public & private per capita expenditure for pharmaceuticals and other medical non-durable goods (2021)

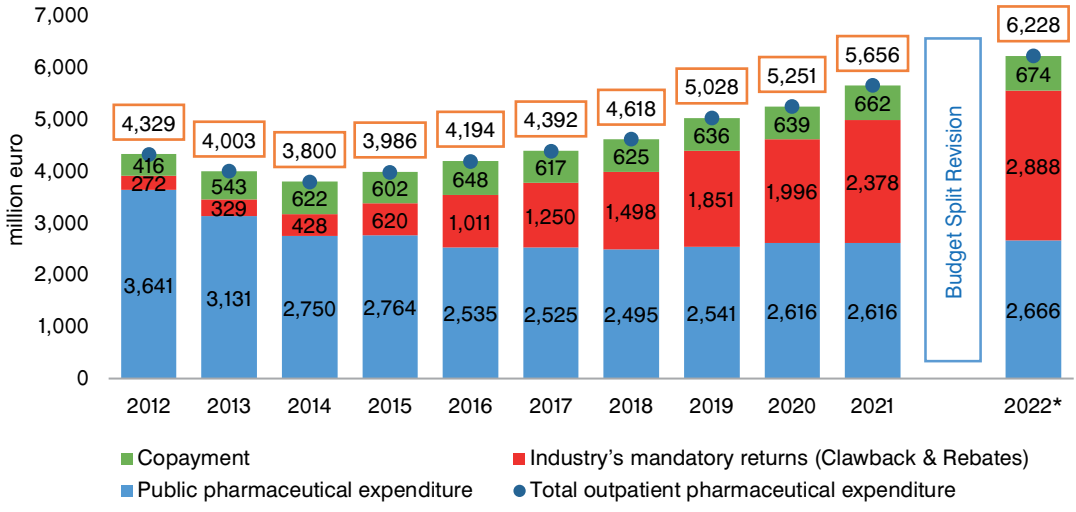


SOURCE: OECD Health Statistics, 2023, data processing IOBE.

PHARMACEUTICAL EXPENDITURE (EOPYY)

Public pharmaceutical expenditure amounted to €2.6 billion in 2021, maintaining the same levels as last year, while is expected a marginal increase in public expenditure to €2.7 bil. for 2022. Conversely, the mandatory returns (clawback and rebates) that the pharmaceutical industry paid in 2021 amounted to €2.4 bil., compared to €2.0 bil. in 2020. At the same time, patients' contribution to reimbursed medicines also recorded an increase and is estimated to reach €689 mil. in 2022. According to calculations, industry's total mandatory returns will exceed the public pharmaceutical expenditure for 2022.

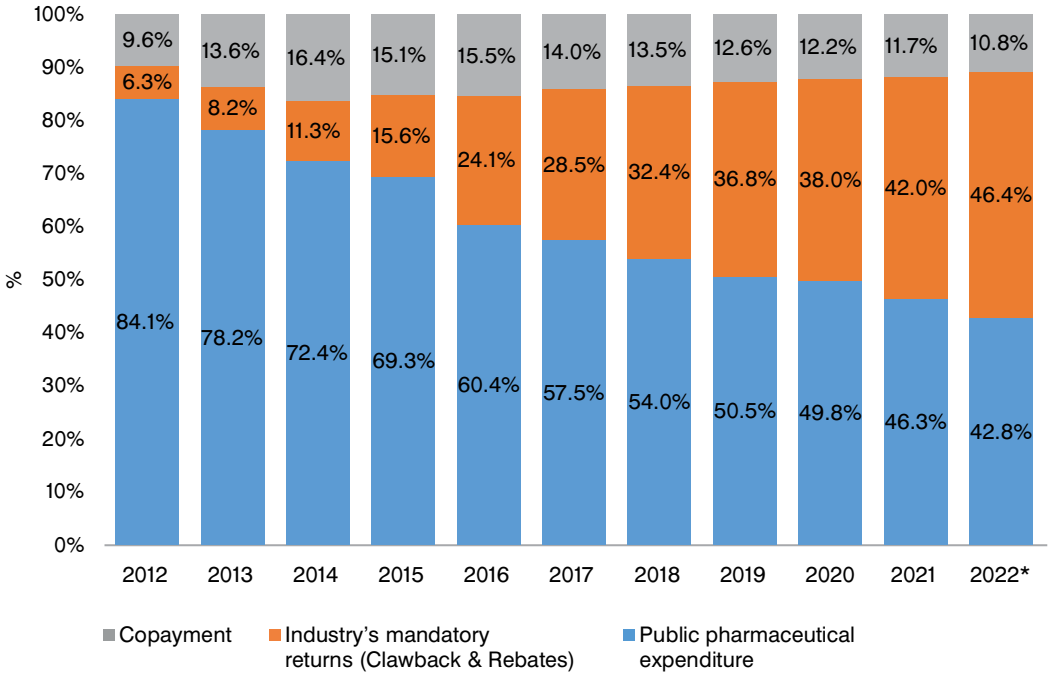
Figure 27: Pharmaceutical expenditure (Industry's mandatory returns and patients' contribution)



SOURCE: EOPYY 2012-2022, data processing IOBE-SFEE, Note: Direct payments (out of pocket) are not included. *For 2022 the clawback and rebates are estimations. Public pharmaceutical expenditure includes closed retail sub-budgets +1B, Hospitals ESY, EOPYY 1A, the closed budget and Papageorgiou Hospital. Industry's mandatory returns includes clawbacks, rebates, and discounts on closed sub-budgets. Patient participation is only what the patient pays in the reimbursed market (ie the statutory 0%, 10%, 25%) and the charge resulting from the difference between Retail Price (LT) and Compensation Price (TA).

Continuous underfunding has increased the contribution share of the pharmaceutical industry to 46% of total public expenditure, making the pharmaceutical industry an additional informal pillar of pharmaceutical financing.

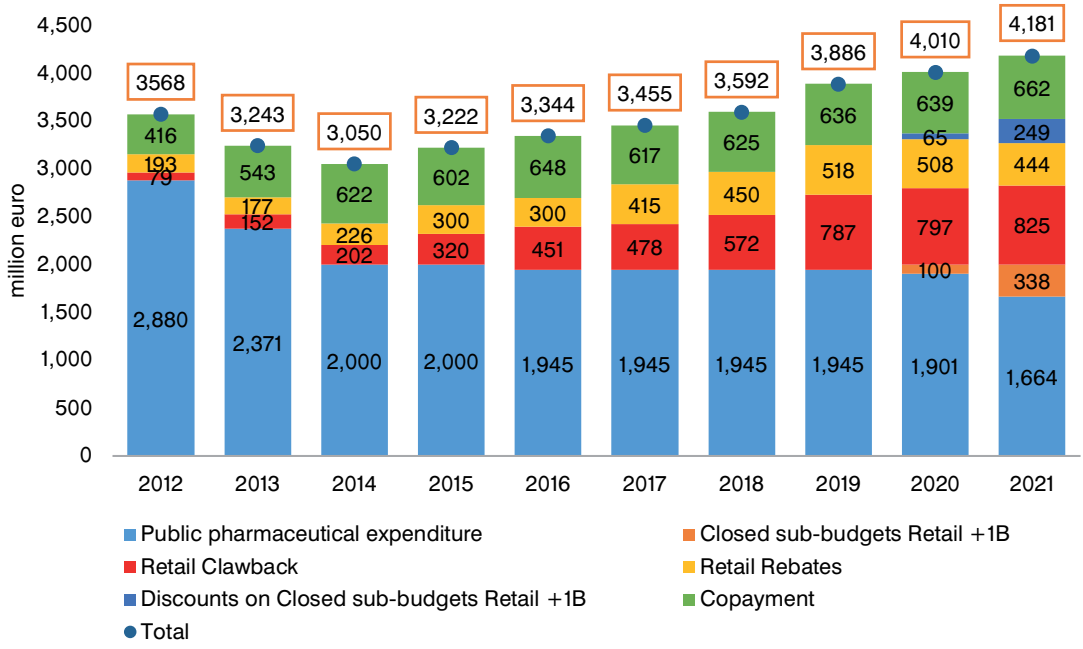
Figure 28: Share of public pharmaceutical expenditure



SOURCE: EOPYY 2012-2022, IOBE-SFEE data processing. Note: Direct payments (out of pocket) are not included. *For 2022 the clawback and rebates are estimations.

Total outpatient pharmaceutical expenditure (including estimated patients' and industry contribution) reaches €4.2 bil. in 2021. Public expenditure (together with closed retail sub-budgets) stood at €2.0 billion in 2021, stable from 2020. Industry's mandatory returns (clawbacks, rebates, and discounts on closed sub-budgets) amounted to €1.5 bil.in 2021, compared to €1.4 billion in 2020 and €272 mil. in 2012. The reduction in public pharmaceutical expenditure in the period 2012-2021 by approximately 31% resulted in a significant increase of industry contribution over the same period by 458% and of patients by 59%.

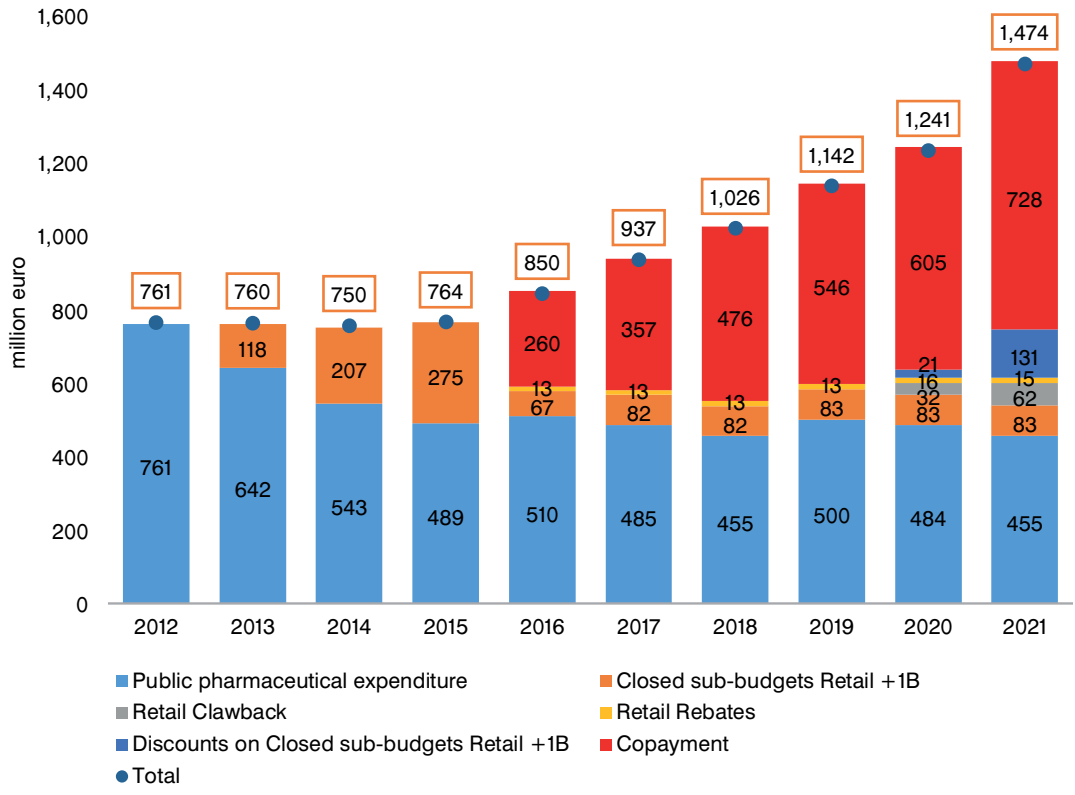
Figure 29: Total public and private outpatient pharmaceutical expenditure per category



Source: EOPYY 2012-2021, data processing IOBE-SFEE, Note: Direct payments (out of pocket) are not included. Public pharmaceutical expenditure also includes closed retail sub-budgets +1B. Industry's mandatory returns include clawbacks, rebates, and closed sub-budget discounts. 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 €553 mil. for 2021, decreased by -13.1% compared to 2015 (€764 mil.), before the imposition of a closed budget. The continuous reduction of public hospital pharmaceutical expenditure resulted in an increase in the contribution of the pharmaceutical industry (through mandatory reimbursement mechanisms and mandatory returns and discounts (clawback and rebates), estimated at €728 mil., compared to €260 mil. in 2016

Figure 30: Public hospital pharmaceutical expenditure and industry's contribution



SOURCE: EOPYY 2012-2022, data processing IOBE-SFEE. Note: Estimations for 2021 for industry's contribution. EOPYY (1A) include Aretaeio hospital. Public pharmaceutical expenditure includes the closed retail sub-budgets +1B, the ESY Hospitals, EOPYY 1A, the closed budget and Papageorgiou Hospital. Industry's mandatory returns includes clawbacks, rebates, and discounts on closed sub-budgets

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.

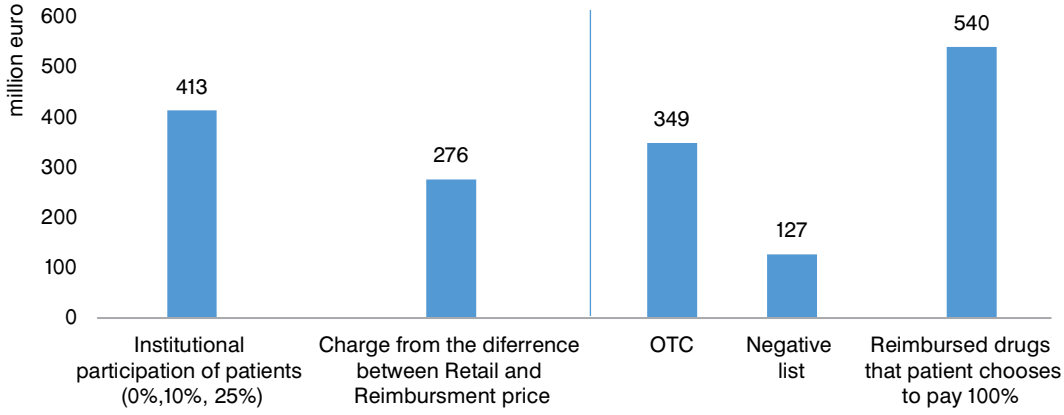
Patient co-payment in reimbursed medicines is distinguished in:

- "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 31: Total private pharmaceutical expenditure (2022)



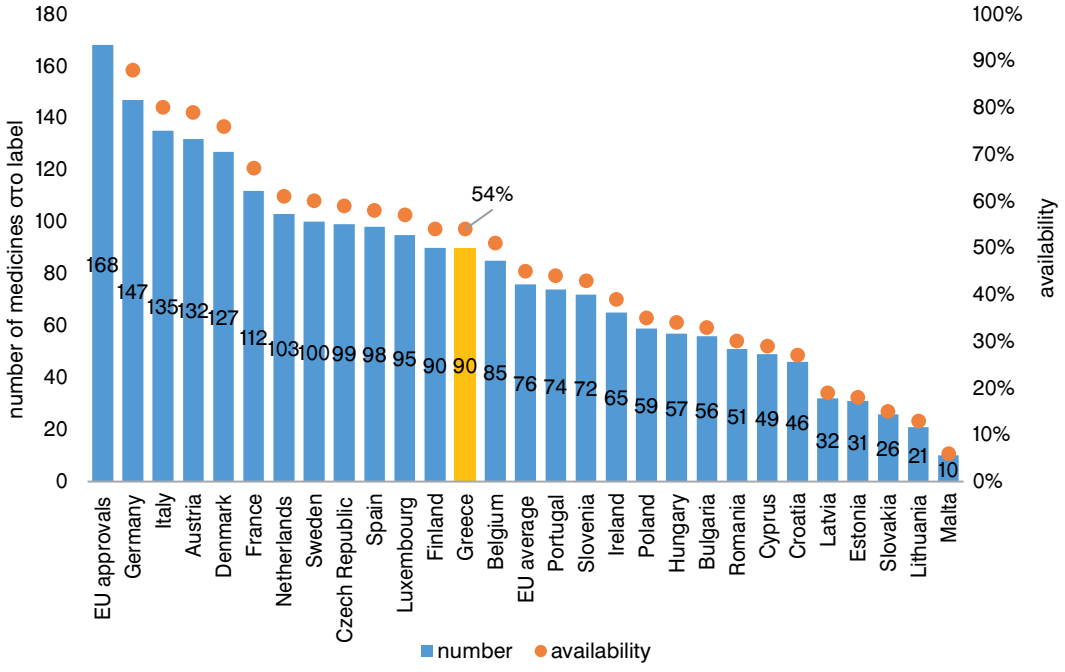
SOURCE: Data from IDIKA (Institutional Patient Participation), OTC and Negative list, SFEE calculations based on EOPYY and IQVIA (Q4/2021). The data for 2022 of patient participation are estimations.

3.3 PATIENT ACCESS TO INNOVATIVE THERAPIES

The availability of innovative medicines and the time for patients to access innovative treatments varies significantly from country to country, which creates inequalities in patient access to new treatments. The European Federation of Pharmaceutical Industries (EFPIA), attempting to examine the degree of patient access to new innovative treatments, has been conducting annual surveys since 2004, taking into account the W.A.I.T. (Waiting to Access Innovative Therapies) of the two individual indicators of the W.A.I.T. study: a) the availability of new innovative therapies and b) the time required from the date of their approval by the EMA to the date of their reimbursement by the health systems.

According to the latest study published in April 2023, for the period 2018-2021, of the 168 innovative medicines that received a central authorization from EMA, 90 preparations are available to the Greek patient, i.e. 54% of the approved innovators medicines compared to 47% which is the EU average (Chart 32).

Figure 32: Rate of availability of new medicines (2018-2021)

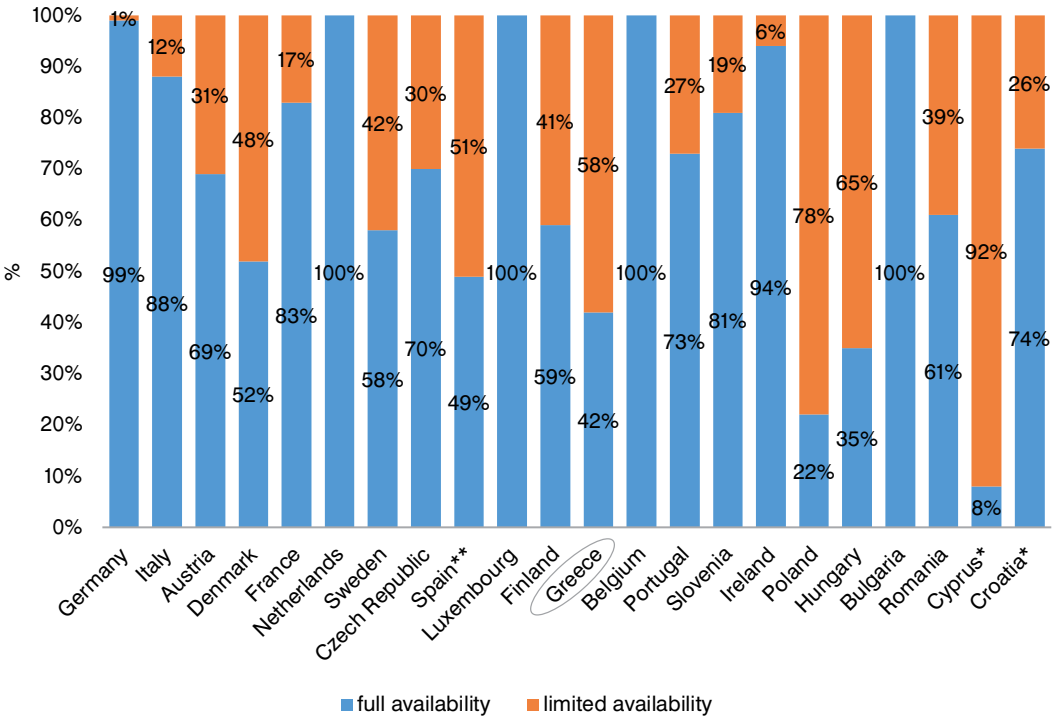


SOURCE: EFPIA W.A.I.T Indicator April 2023, European Union average: 76 products available (45%).In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme.*Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

The **rate of availability of innovative treatments for the years 2018-2021** refers to the number of medicines available to patients in European countries on 5 January 2023. For most countries, this is the point at which the product is entered into the reimbursement list, including of pharmaceutical products with limited availability.

Accordingly, **the degree of availability of innovative treatments for the years 2018-2021(%) according to diagram 33**, captures the percentage of medicines available to patients in European countries on January 5, 2023 (for most countries this is the point in which the medicinal product is entered into the reimbursement list) without restrictions on the patient population or through named patient base systems.

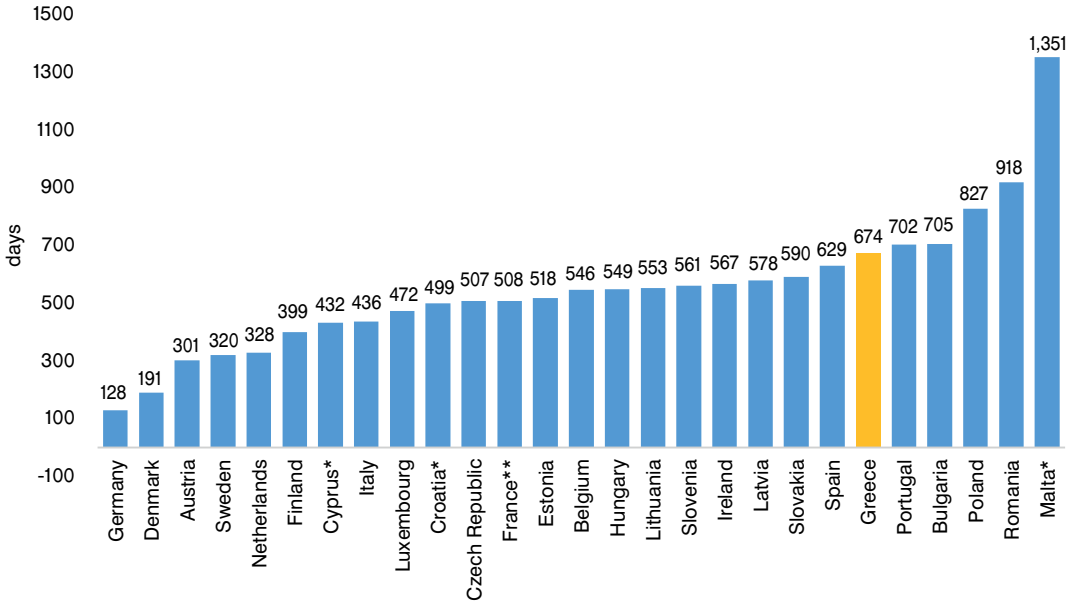
Figure 33: Rate of full availability (%, 2018-2021)



SOURCE: EFPIA W.A.I.T Indicator April 2023, European Union average: 76 products available (45%), Limited Availability (37% of available products) Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. ¶ In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

In more detail, while at the European level the availability of new innovative medicines appears satisfactory compared to the average, the majority of reimbursed medicines appear to be of limited and not full availability. In particular, 58% of the new medicines available in Greece, compared to the European average of 37%, are under a limited availability or reimbursement regime, mainly reflecting the medicines that are available through IFET and the Electronic Pre-Authorization System (EPS). Finally, regarding the time required from the date of approval of the drugs by the EMA to the date of their reimbursement by the health systems, Greece significantly lags behind the reimbursement time of a new treatment compared to the European average, as according to the study, this is calculated equal to 674 days (versus 517 days in the EU countries).

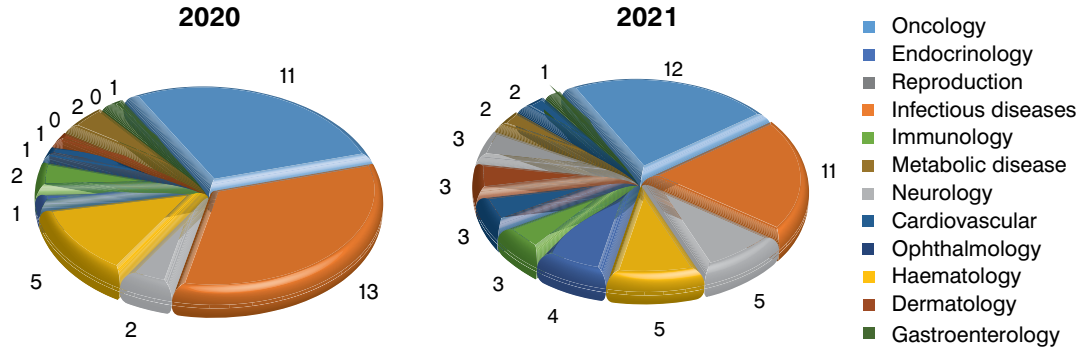
Figure 34: Time from central approval to availability (2018-2021)



SOURCE: EFPIA W.A.I.T Indicator April 2023, European Union average: 517 days (mean %) (Note: Malta is not included in EU27 average as only 2 dates were submitted in total) ¶ In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (508 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

The number of new active substances approved by the European Medicines Agency (European Medicines Agency-EMA) in 2021 (54 new approvals) increased by 38.5% compared with 2020 (39 approvals).

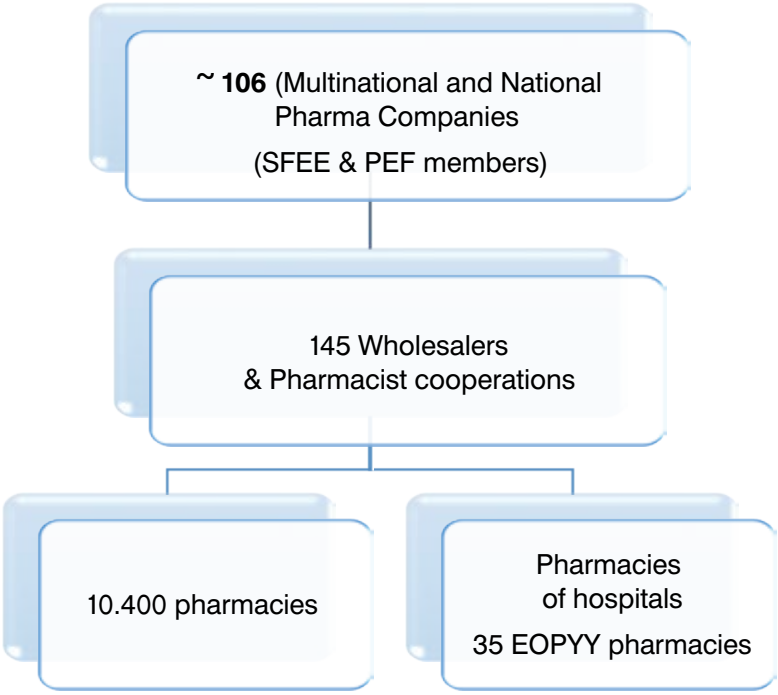
Figure 35: New medicine approvals 2020-2021



SOURCE: IQVIA, EFPIA Pipeline Innovation Review 2022

4.1 SUPPLY CHAIN FOR PHARMACEUTICAL PRODUCTS IN GREECE

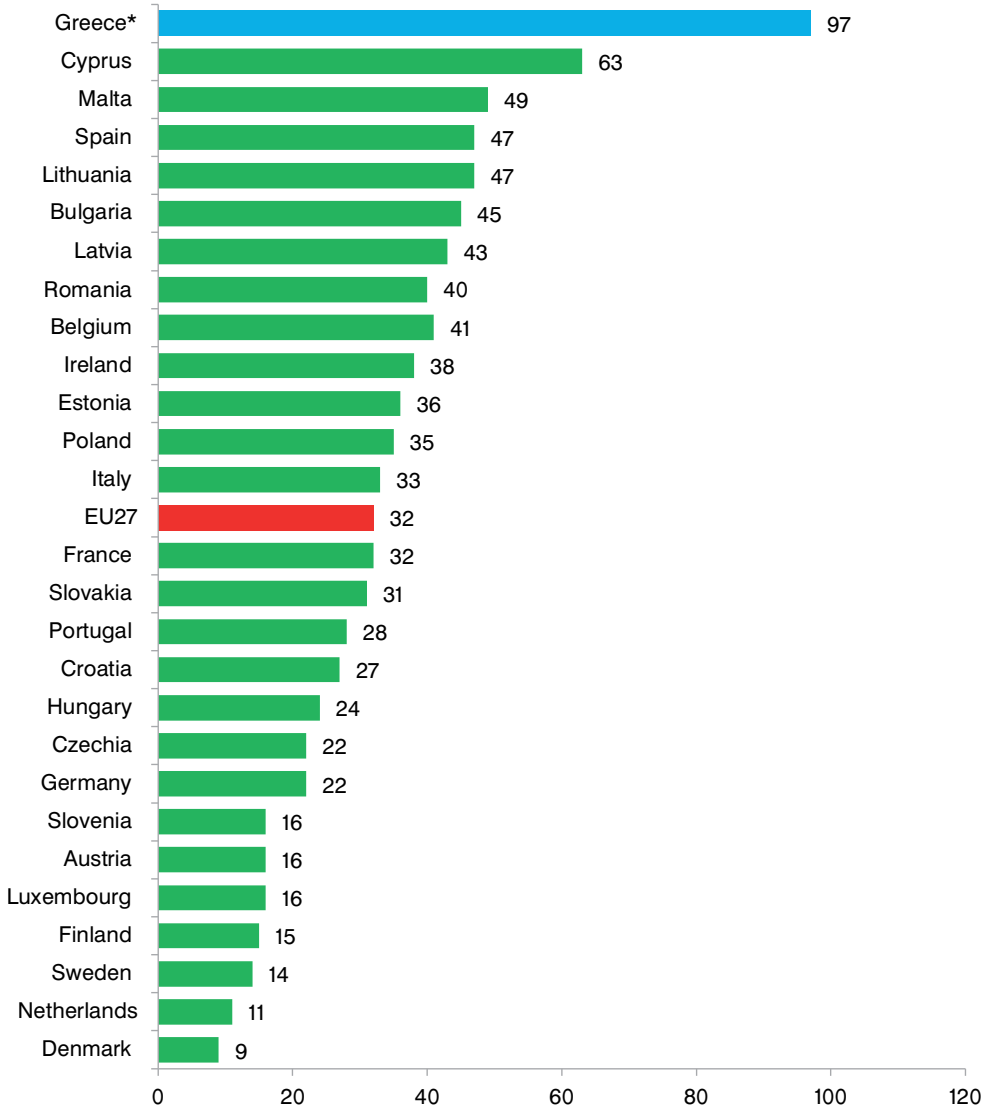
The production and distribution of pharmaceuticals is one of the most dynamic sectors in the Greek industry. The supply chain for pharmaceutical products is comprised of pharmaceutical companies (both manufacturers and importers), wholesalers (both storage and distribution) and pharmacies. More specifically,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



SOURCE: ELSTAT, EOPYY, PanHellenic Association of Pharmaceutical Wholesalers

With a pharmacy density of 97 pharmacies per 100.000 inhabitants, Greece comes first in 2021 among the EU-27 average of 32 pharmacies per 100.000 inhabitants.

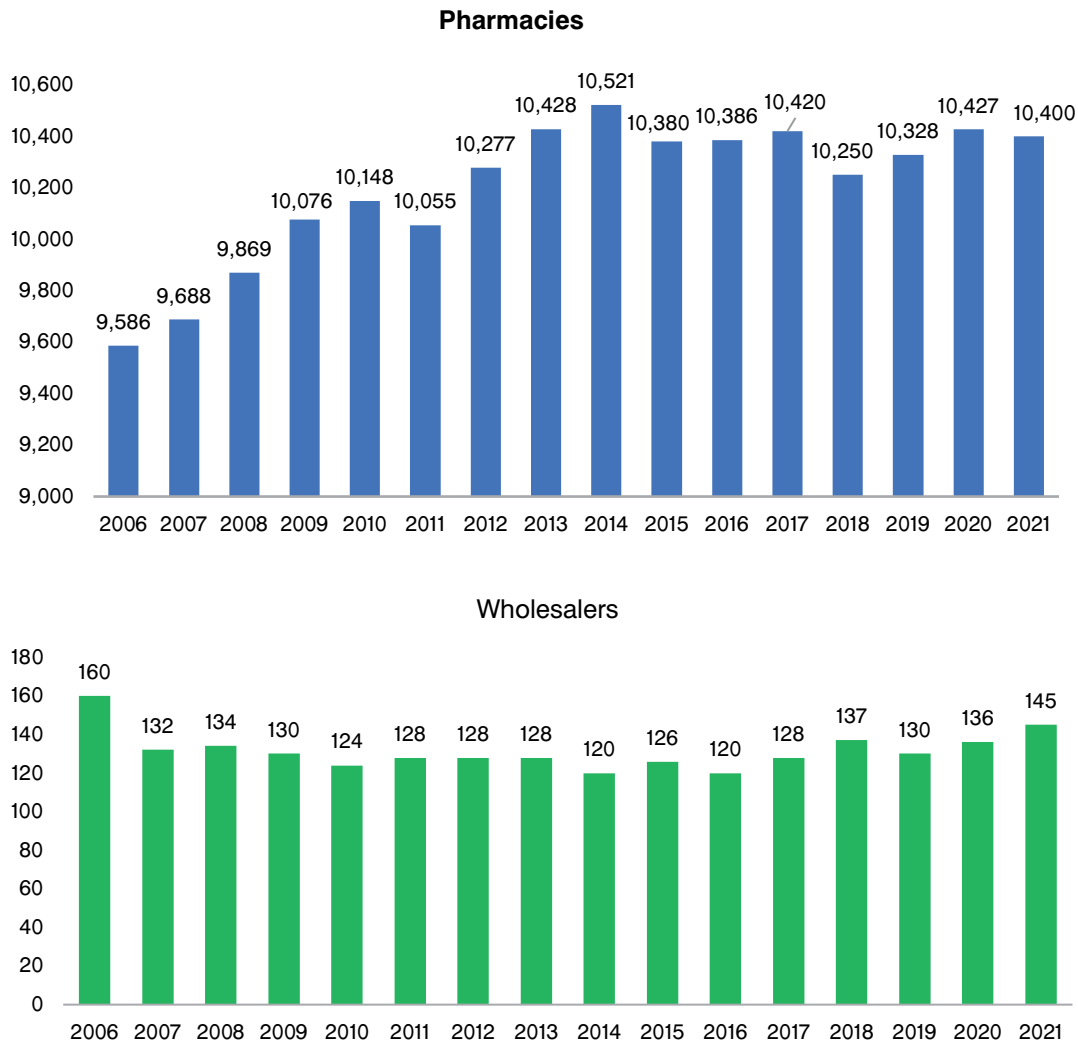
Figure 36: Number of pharmacies per 100.000 inhabitants, EU27 (2021)



SOURCE: ABDA. German Pharmacies, Figures Data Facts 2022, ELSTAT., 2022 * Data for Greece come from the latest available ELSTAT. data.

In 2021, 10,400 pharmacies operated in Greece, out of which 3,676 pharmacies (35.3%) were in the Region of Attika. The number of wholesalers increased from 136 in 2020 to 145 in 2021.

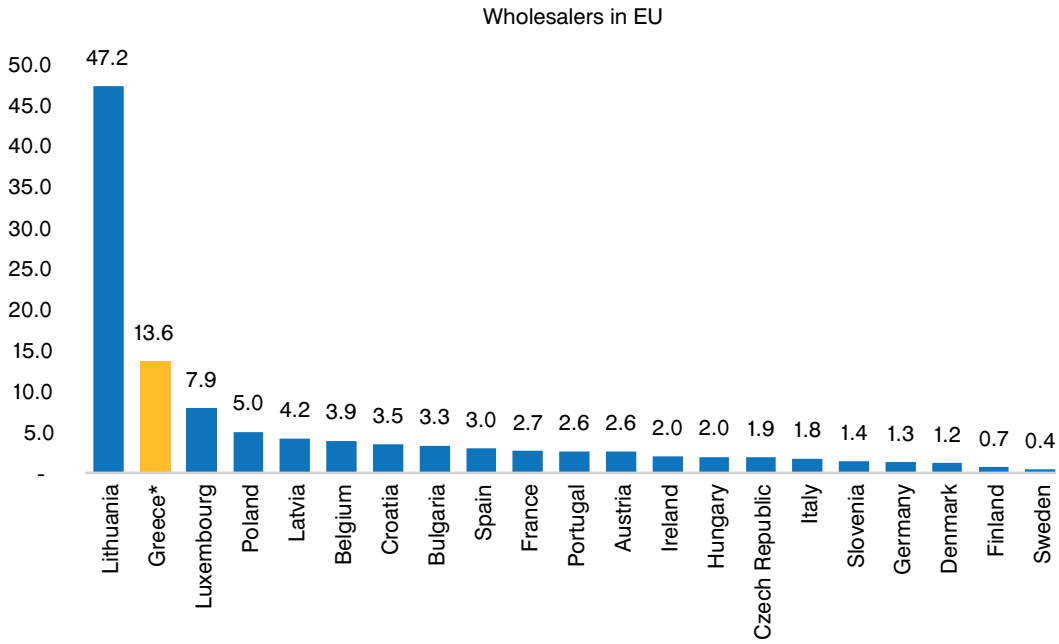
Figure 37: Pharmacies and wholesalers- Greece



SOURCE: ELSTAT, 2022

The wholesale market for pharmaceuticals is fragmented in Europe. In several European countries there are 10-30 pharmaceutical wholesalers on average, while in Greece there are 145 private pharmaceutical wholesalers and cooperatives. Pharmaceutical wholesalers in Greece account approximately in 14 per 1 million inhabitants, higher than any other country except Lithuania.

Figure 38: Wholesalers per 1 million inhabitants EU22



SOURCE: GIRP 2021-2022, * Greece data from ELSTAT, data processing IOBE

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, 35 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.

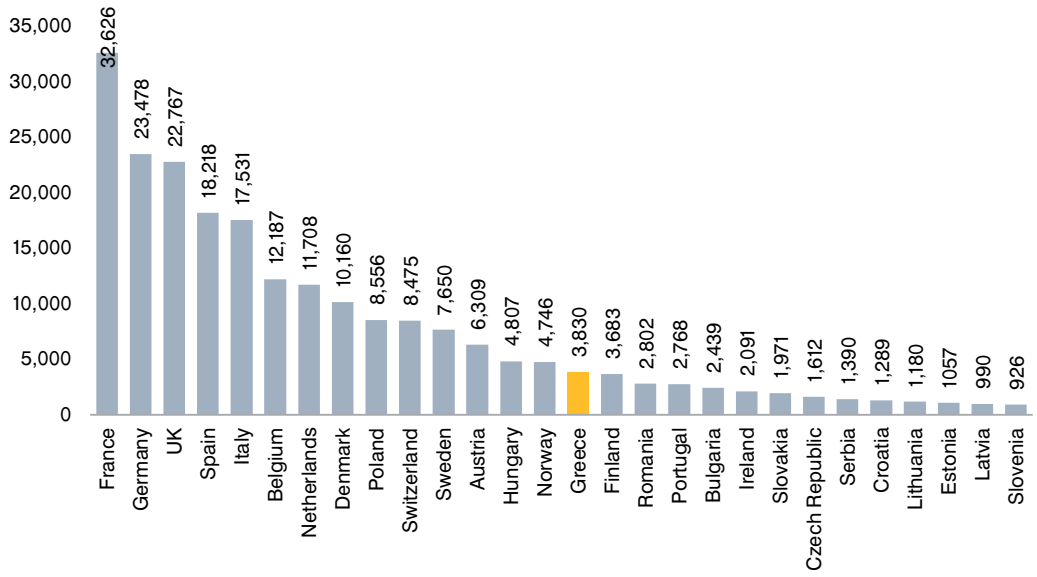
Since January 2016, under the new legislative regulation for hospital clawback (N. 4354 / 12.16.2015, Section D, Article 41), all high-cost medicines that their use is hospital only (Annex 1A) are exclusively administered from pharmacies in public hospitals.

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)

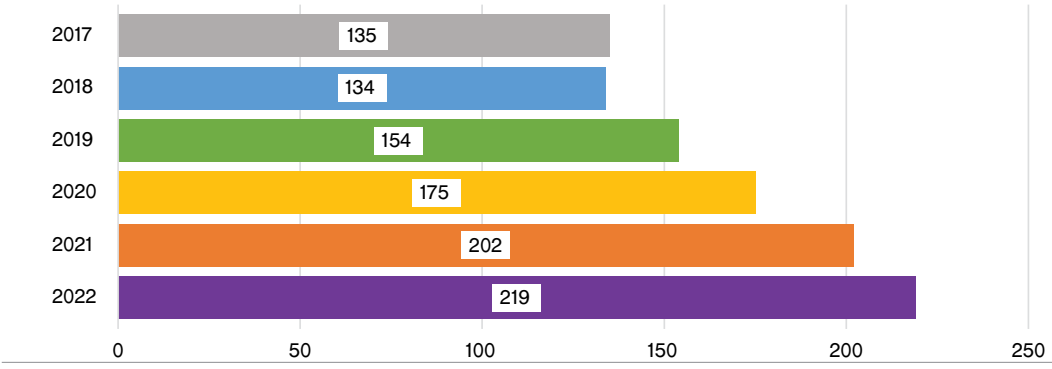
In Greece, 3,830 clinical studies (2,250 completed) were conducted from 2002 up to 2022 (all types and phases).

Figure 39: Total number of clinical trials, all phases and stages (2002-2022)



SOURCE: Clinical trials.gov, 2022

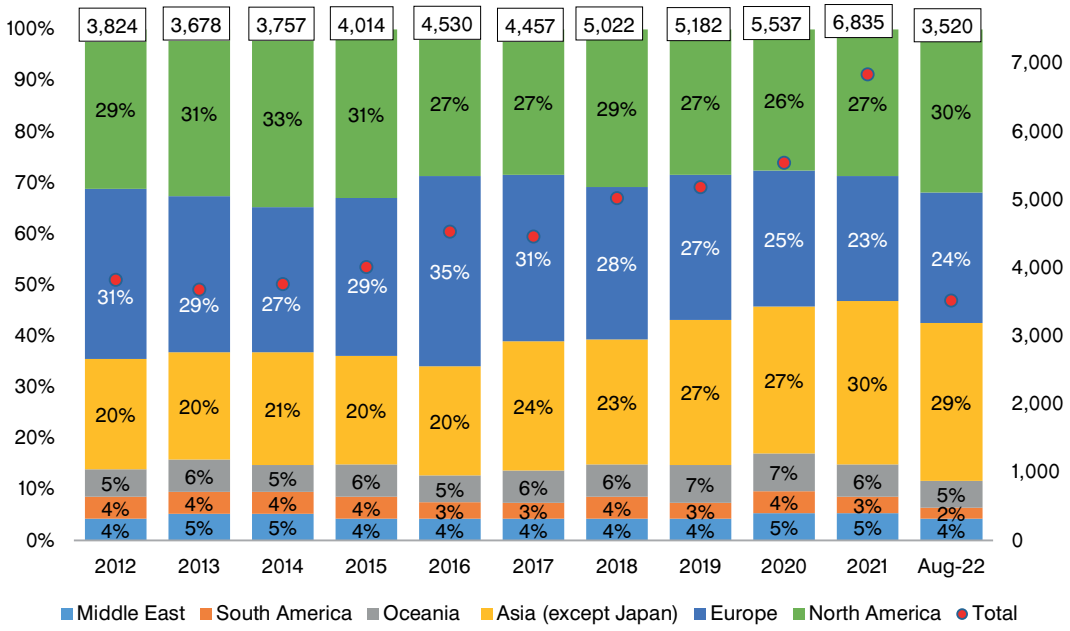
Figure 40: Total number of clinical trials by year, Greece (2017-2022)



SOURCE: SFEE

At a global level, Europe notes a decline compared to North America and Asia in the number of clinical studies from 2019 onwards. Europe accounts for 24% of total clinical studies for 2022 versus 30% for North America and 29% for Asia.

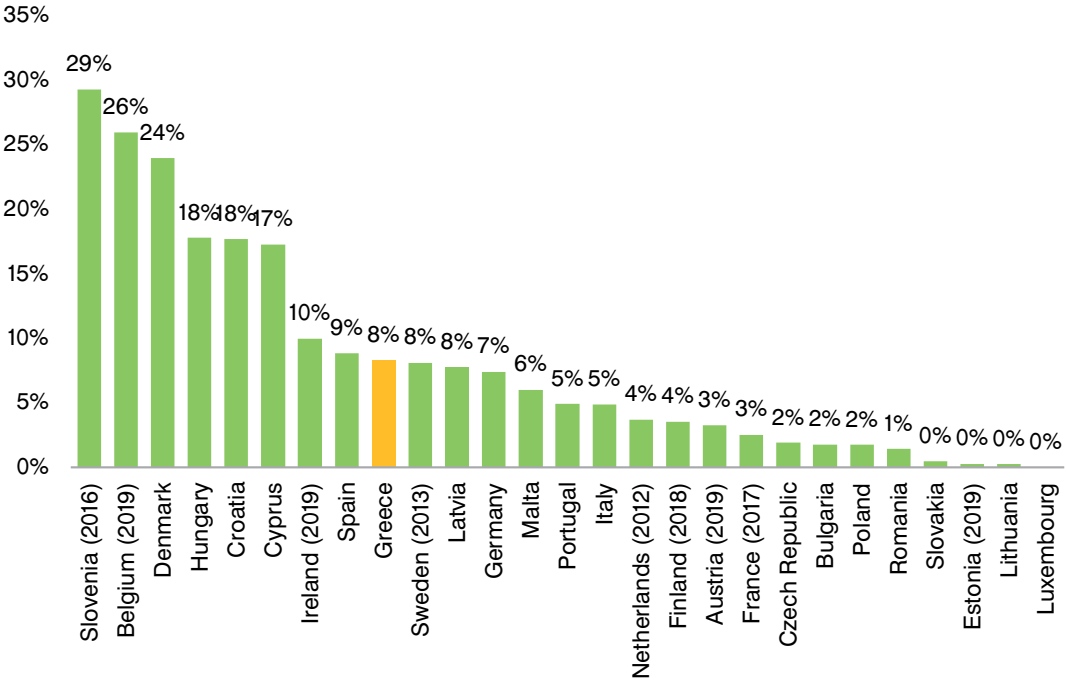
Figure 41: Total number of clinical studies by geographic region (2012-2022)



SOURCE: IQVIA, EFPIA Pipeline Innovation Review 2022

The expenditure of the pharmaceutical industry on R&D reached €95 mil. (from €76 mil. in 2019 and €51 mil. in 2017) and corresponds to 8% of the total expenditure on R&D in Greece, a percentage higher than 2019 (7%).

Figure 42: Pharmaceutical R&D expenditure (% of total R&D expenditure) (2020)

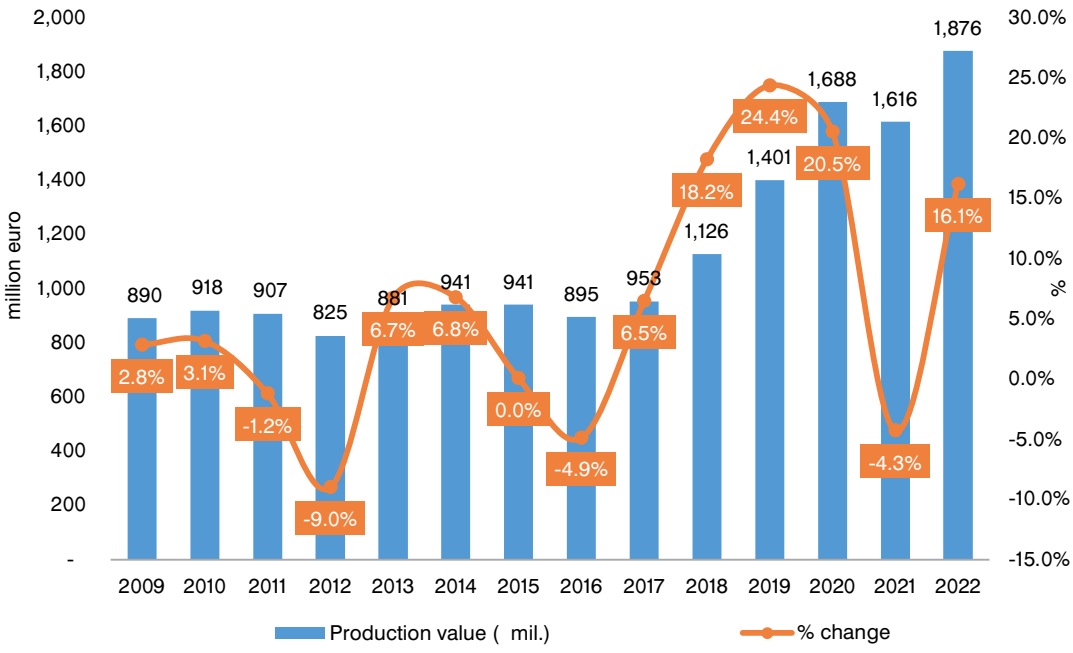


SOURCE: Eurostat, 2023, data processing IOBE

4.3 PRODUCTION

According to Prodcom database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece considered to €1.9 bil. in 2022, increased compared to 2021 by 16.1%, while the production is double compared to the average of the period 2009-2017 (€906 million).

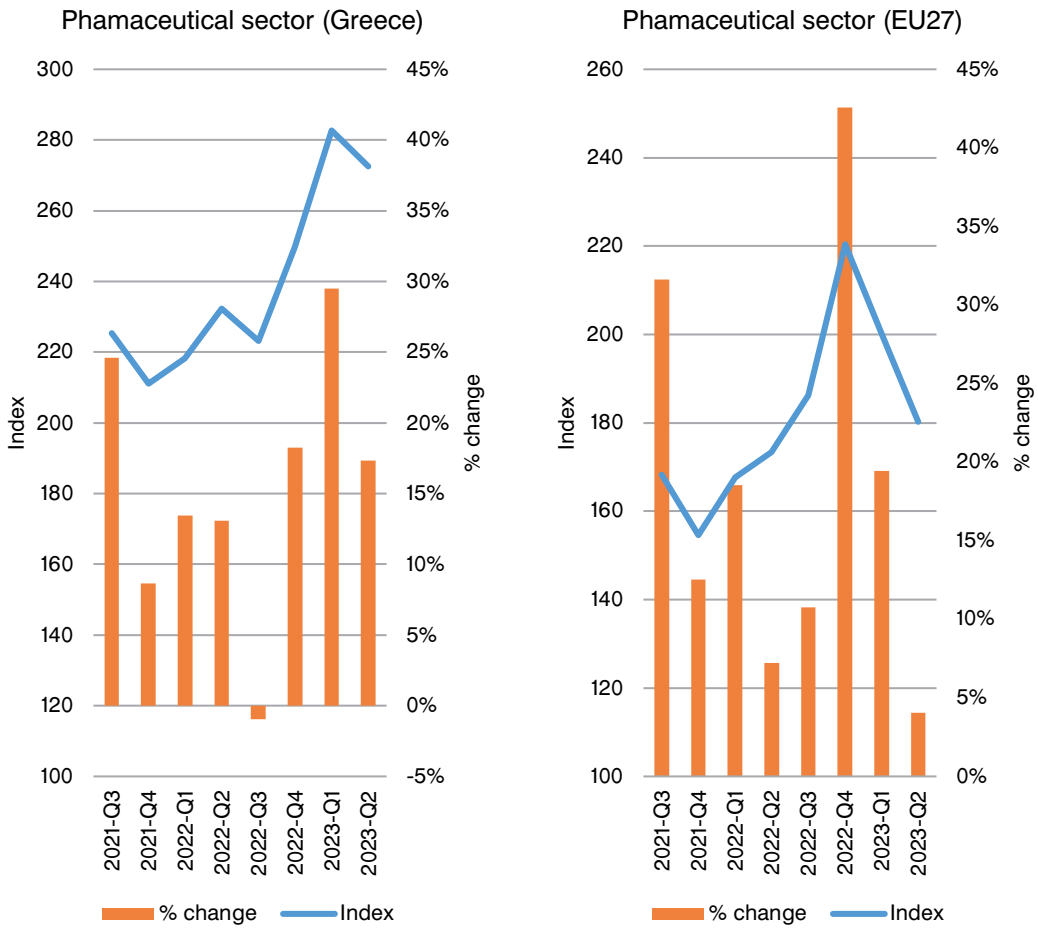
Figure 43: Production of pharmaceutical products (mil. €)



SOURCE: Eurostat 2023, PRODCOM Database, data processing IOBE. *Any changes based upon review of data from Eurostat

The index of industrial production of pharmaceuticals increased in 2022 with a significant strengthening in the fourth quarter of the year, while it continued its upward trend in early 2023. The index of production in the EU27 average had a similar trend, with a significant expansion in the fourth quarter of 2022 by 42%, while it continued to grow with less intensity in early 2023.

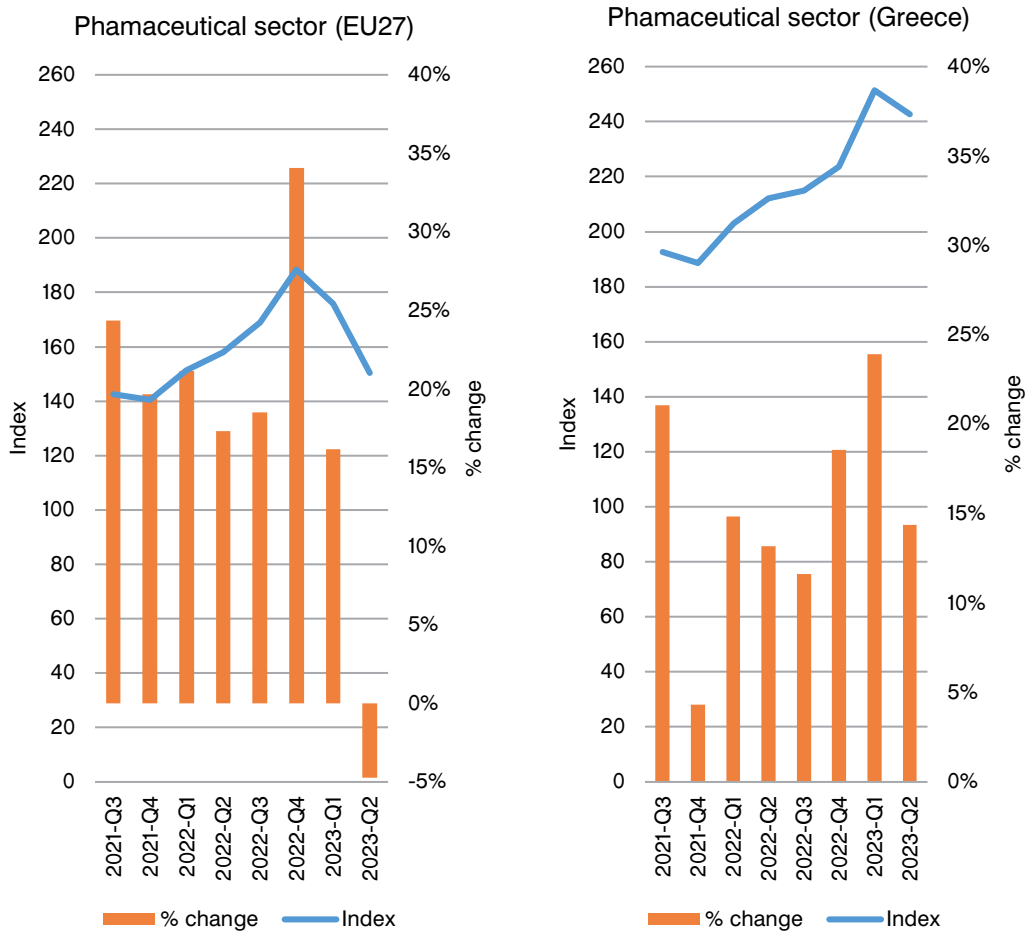
Figure 44: Industrial index of pharmaceutical production (2015=100)



SOURCE: Eurostat, 2023, seasonally adjusted and adjusted data by working days, data processing IOBE

The turnover of the production of pharmaceutical products also registers a continuous upward trend in 2022 as well as in the beginning of 2023. The turnover index in the EU27 recorded an increase in the end of 2022 to 189 units, against 141 units in 2021, with an increase of 34%, while there is a decline in the second quarter of 2023.

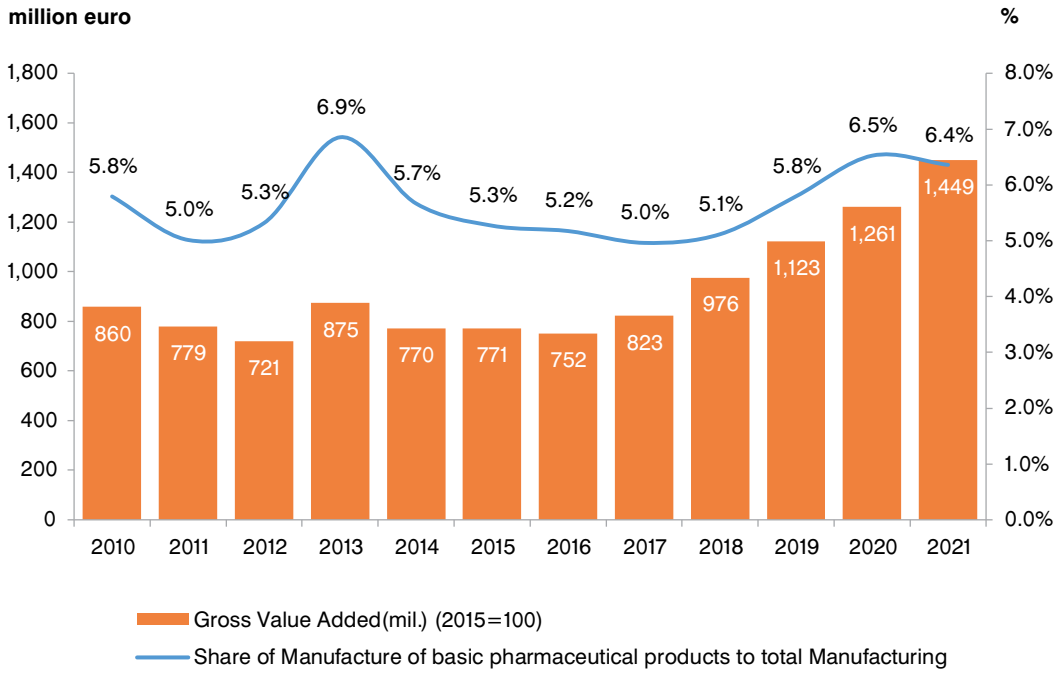
Figure 45: Turnover index of the pharmaceutical production (2015=100)



SOURCE: Eurostat, 2023, seasonally adjusted and adjusted data by working days, data processing IOBE

The Gross Value Added (GVA) of the domestic pharmaceutical sector is estimated at €1.45 bil. in 2021, amounted with a share of 6.4% in total manufacturing sector in national accounts terms, showing an upward trend since 2017.

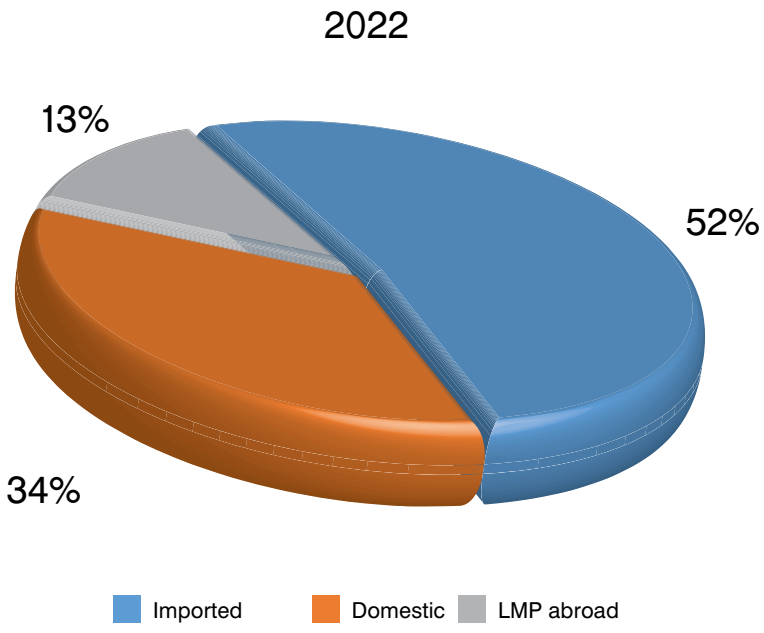
Figure 46: Gross Value Added of pharmaceutical production and share in manufacturing (%)



SOURCE: Eurostat, 2023, 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 highly educated personnel, while with appropriate incentives, domestic production of international pharmaceutical products may increase.

Figure 47: Percentage of pharmaceutical production in Greece and abroad (in market volume)

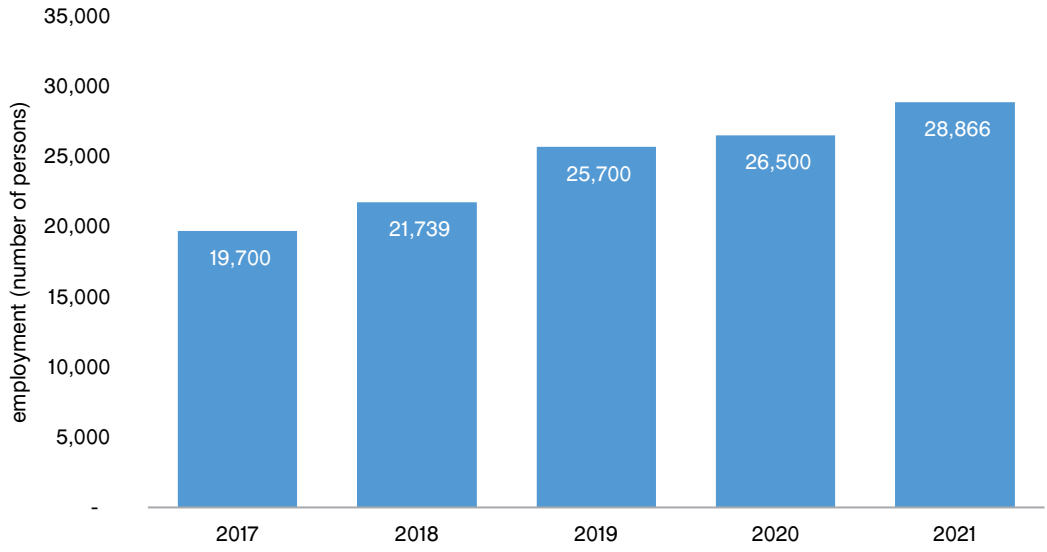


SOURCE: IQVIA 2023, *Locally Manufactured products LMP abroad = Products of international companies manufactured / packaged in Greece * Factories: 28 Greek-owned factories and 1 foreign-owned factory

4.4 EMPLOYMENT

In Greece, total employment in the pharmaceutical sector approached 29 thousand persons in 2021, with a clear upward trend, while in 2020 employment in the wider sector was at 26.5 thousand. In the period 2017-2021, the sector has added approximately 9 thousand employees.

Figure 48: Employment in pharmaceutical sector



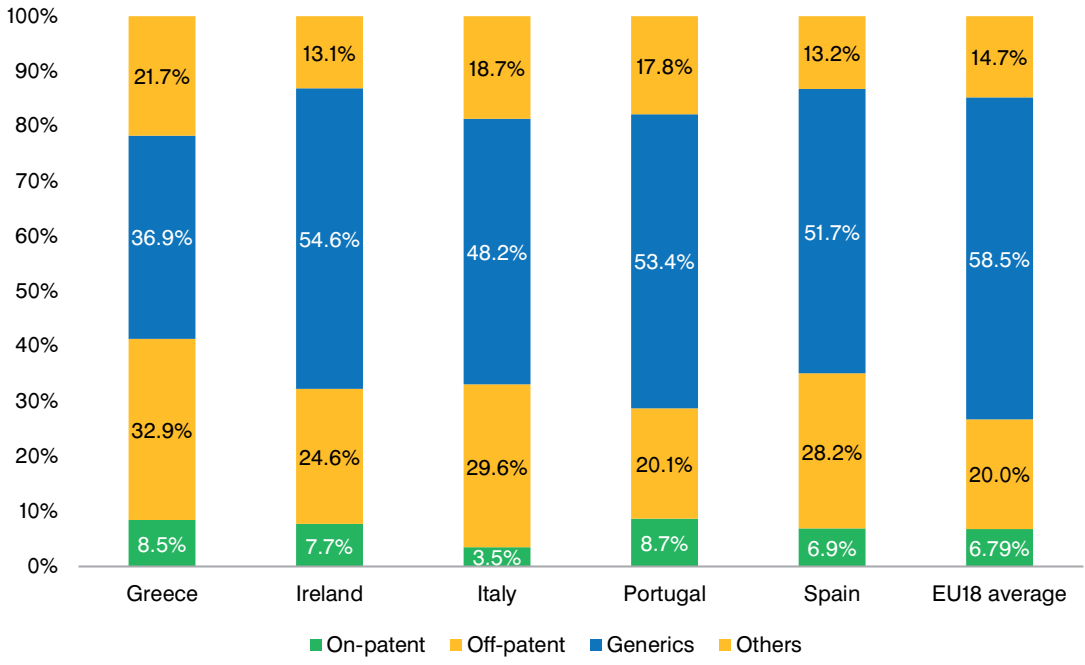
SOURCE: Eurostat 2023, Labour Force Survey, 2023, Estimations IOBE-SFEE, ICAP, processing IOBE * Data for sectors 21.1 Manufacture of basic pharmaceutical products and 21.2 Manufacture of pharmaceutical preparations are included, employees in the wholesale sector of the wider health sector are not included

4.5 PHARMA MARKET STRUCTURE

Pharmaceutical products can be classified according to their patent protection status. According to IQVIA, 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 (6.8%) which can be partly justified by their significantly lower prices in Greece compared to EU18 countries (€0.97 per unit on average compared to €1.95)

Respectively, the market share of non-protected pharmaceutical products amounted to 69.8% (off- patent 32.9% and generics 36.9%). It is worth noting that the penetration rate of off-patent is higher than the average of EU18 (20.0%), while penetration rate of generics is much lower than the average of EU18 (58.5%).

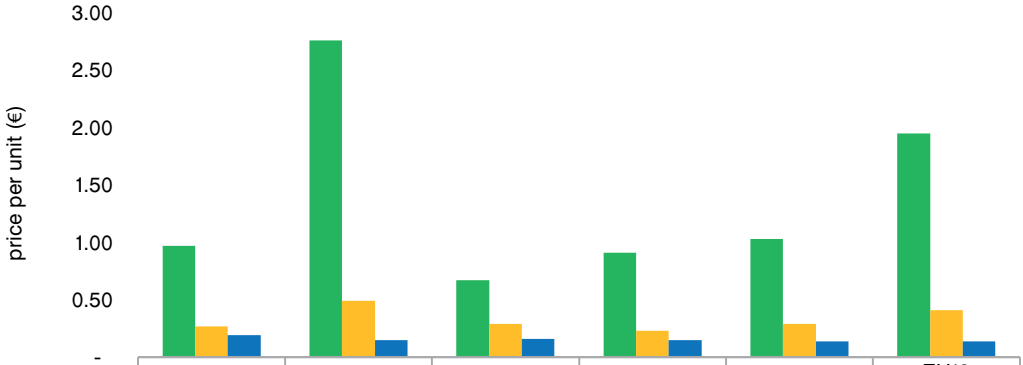
Figure 49: Penetration of pharmaceuticals in EU18, 2022 (in volume) based on patent status



SOURCE: IQVIA 2022, 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 2022), 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 (€0.27 per unit compared to €0.41) and by slightly higher prices for generic products in Greece compared to the average of EU18 (€0.19 per unit compared to €0.14).

Figure 50: Pricing of pharmaceuticals in EU18, 2022 (price per unit. €) based on patent status

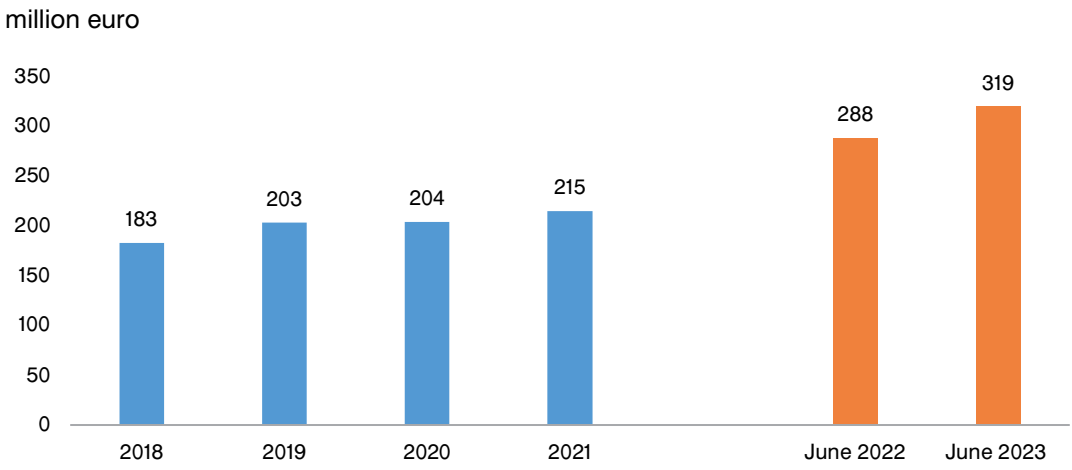


	Greece	Ireland	Italy	Portugal	Spain	EU18 average
On-patent	€0.97	€2.76	€0.67	€0.91	€1.03	€1.95
Off-patent	€0.27	€0.49	€0.29	€0.23	€0.29	€0.41
Generics	€0.19	€0.15	€0.16	€0.15	€0.14	€0.14

SOURCE: IQVIA 2022, 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

The market of OTC in value followed an upward trend from 2018 onwards, from €183 mil. in 2018 reached €319 million in June 2023.

Figure 51: OTC sales in value (mil. €)

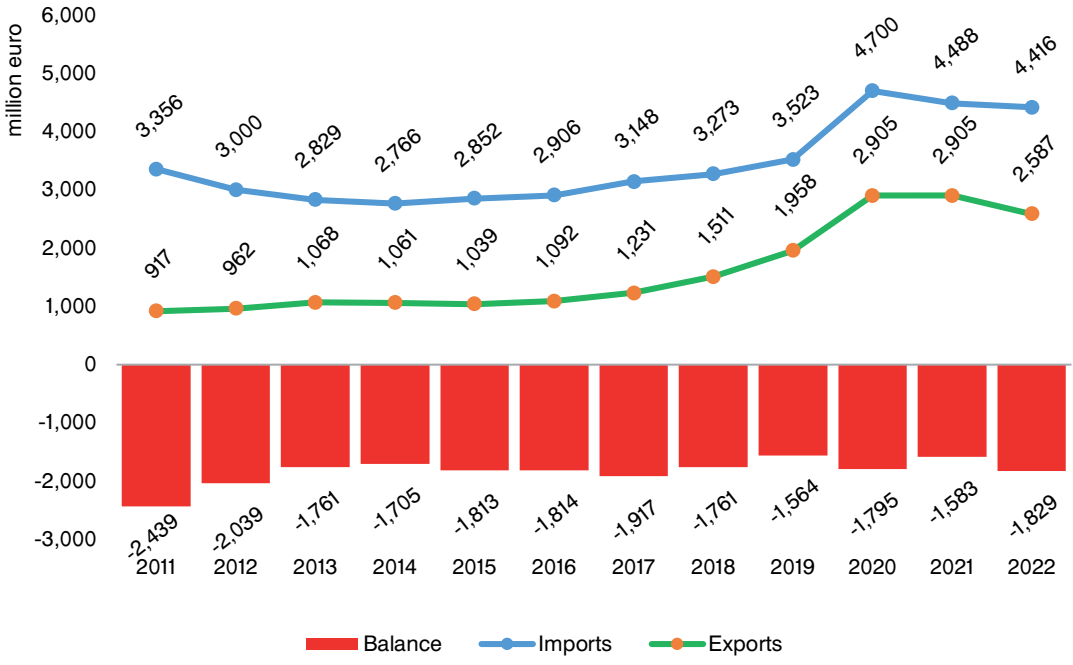


SOURCE: EFEX

4.6 EXTERNAL TRADE

Imports of the pharmaceutical sector amounted to €4.4 bil. in 2022, decreased by 1.6% in comparison to 2021, while the sector's exports decreased to €2.6 bil., resulting in a deficit of €1.8 bil.

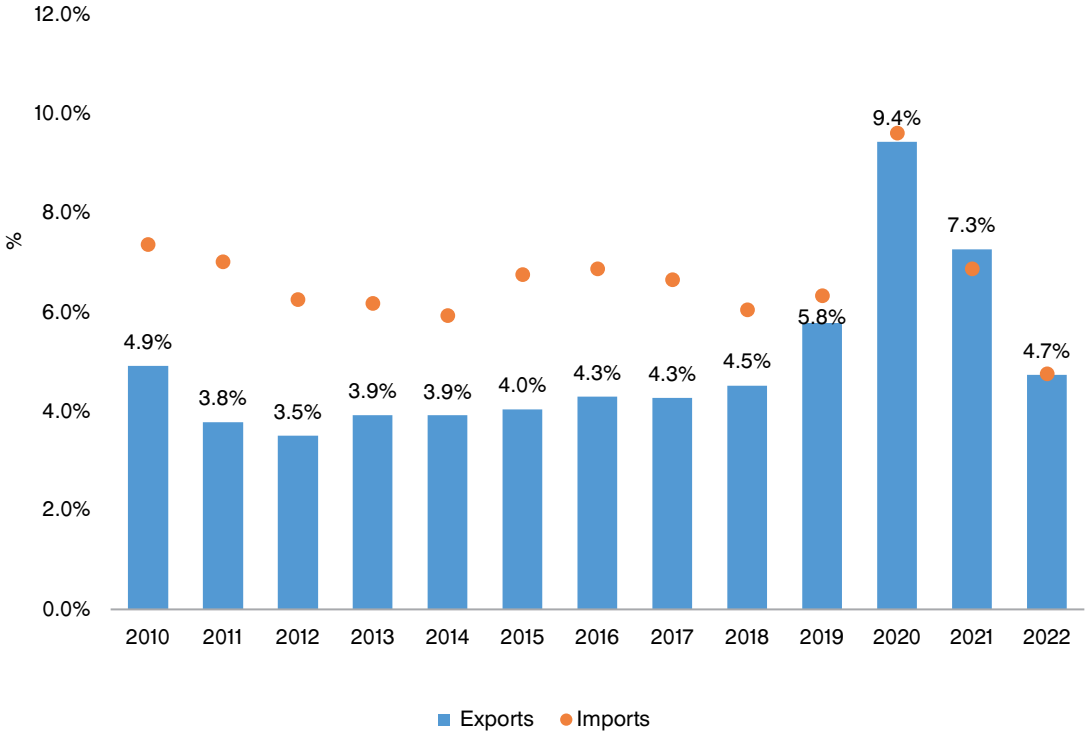
Figure 52: Evolution of pharmaceutical trade balance (mil.€)



SOURCE: Eurostat 2023, International trade, EU Trade Since 1988 By CPA, data processing IOBE

The exports of pharmaceutical products in relation to the total Greek exports, correspond to 4.7% in 2022, remaining close to pre-pandemic levels. Respectively, imports account for 4.7% of total imports of the country in 2022, compared to 6.9% in 2021. The decrease in share is due to the significant increase in fuel and base metals due to the high prices set in 2022.

Figure 53: Share of pharmaceutical exports-imports (% of total exports-imports)-Greece



SOURCE: Eurostat 2023, International trade, EU Trade Since 1988 By CPA, data processing IOBE

Germany remains the first destination country for Greek pharmaceutical exports in 2022 with a share of 15.4%, increased by 15.7% from the previous year, followed by France with a share of 15.0%, registering a significant decrease of 55, 0%. The UK and Cyprus follow with shares of 9.4% and 6.5%, while in the top 10 exports are increased in 2022 compared to 2021 in in Austria, Italy, the Netherlands and Spain.

Table 1: Exports of medicines by country

Country	Exports 2022	Share 2022	% change (2022 vs 2021)	% change (2021 vs 2020)
Germany	397,675,950	15.4%	15.7%	18.4%
France	387,662,602	15.0%	-55.0%	-7.9%
UK	243,543,093	9.4%	47.9%	-13.5%
Cyprus	167,794,919	6.5%	19.3%	14.3%
Austria	133,219,235	5.1%	20.3%	-8.4%
Italy	111,670,286	4.3%	8.3%	8.0%
Netherlands	105,578,642	4.1%	2.9%	32.7%
Spain	89,159,819	3.4%	11.8%	-36.2%
Turkey	76,258,455	2.9%	68.4%	62.2%
South Korea	71,563,333	2.8%	-24.4%	18.9%

SOURCE: Eurostat, International trade, EU Trade Since 1988 By CPA, 2023, data processing IOBE

4.7 PRICING OF PHARMACEUTICALS

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 2: 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 9)	(Table 9)	35%

SOURCE: M.D. (4274/22.11.2019)

Table 3: Percentage of profit (mark-up) pharmacies

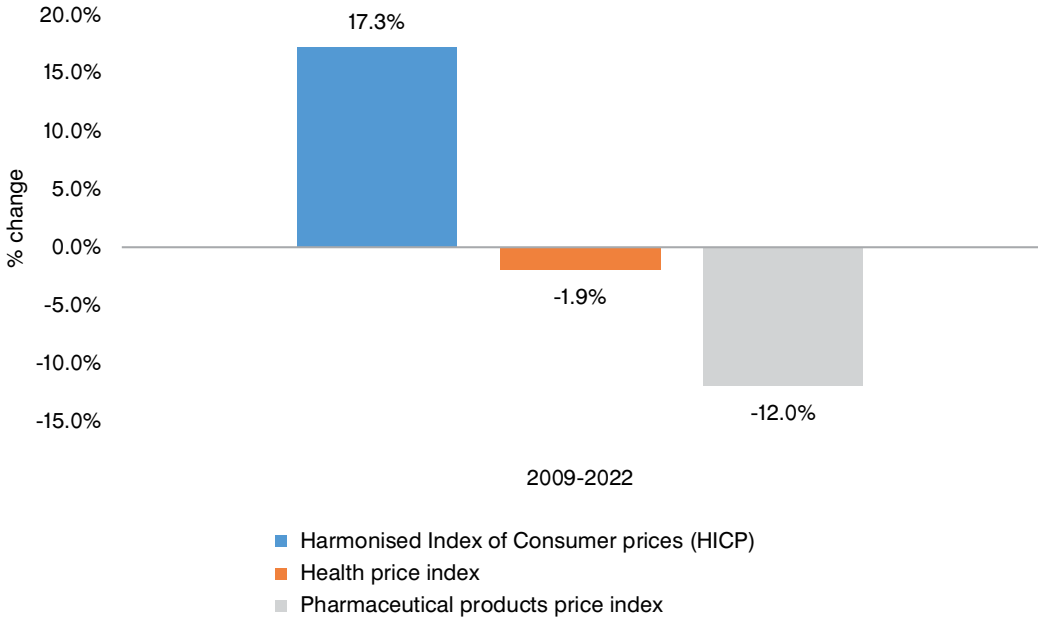
Wholesale price (€)	Percentage	Wholesale price (€)	Percentage
	(mark-up) Φαρμακείου		(mark-up) Φαρμακείου
0 - 50.00	30.00%	900.01 - 1000	5.50%
50.01 - 100	20.00%	1000.01 - 1250	5.00%
100.01 - 150	16.00%	1250.01 - 1500	4.25%
150.01 - 200	14.00%	1500.01 - 1750	3.75%
200.01 - 300	12.00%	1750.01 - 2000	3.25%
300.01 - 400	10.00%	2000.01 - 2250	3.00%
400.01 - 500	9.00%	2250.01 - 2500	2.75%
500.01 - 600	8.00%	2500.01 - 2750	2.50%
600.01 - 700	7.00%	2750.01 - 3000	2.25%
700.01 - 800	6.50%	>3000	2.00%
800.01 - 900	6.00%		

SOURCE: M.D. (4274/22.11.2019)

Additionally, these mark-up margins mentioned above are applied to all reimbursed pharmaceutical 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.

The period 2009-2022, the pharmaceutical price index reduced by 12.0%, the health price index decreased by 1.9%, while general price index increased by 17.3%.

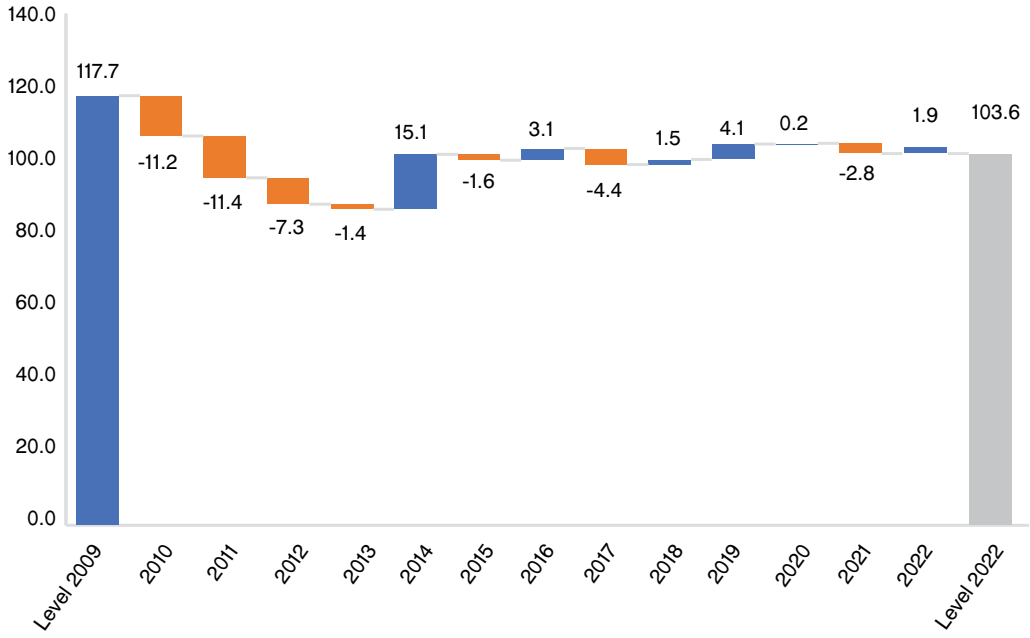
Figure 54: Annual change (%) of HCIP by category (2015=100)



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

The pharmaceutical price index remained at 103.6 points in 2022, versus 117.7 points in 2009, with a continuous decline in the period 2010 2013. An increase was recorded in 2014, 2016, the period 2019-2020 and 2022, however, these increases did not balance the significant declines in the first period, resulting in the decrease of the index by 14.1 points lower between 2022 and 2009.

Figure 55: Annual change (%) of HCIP and index levels (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.

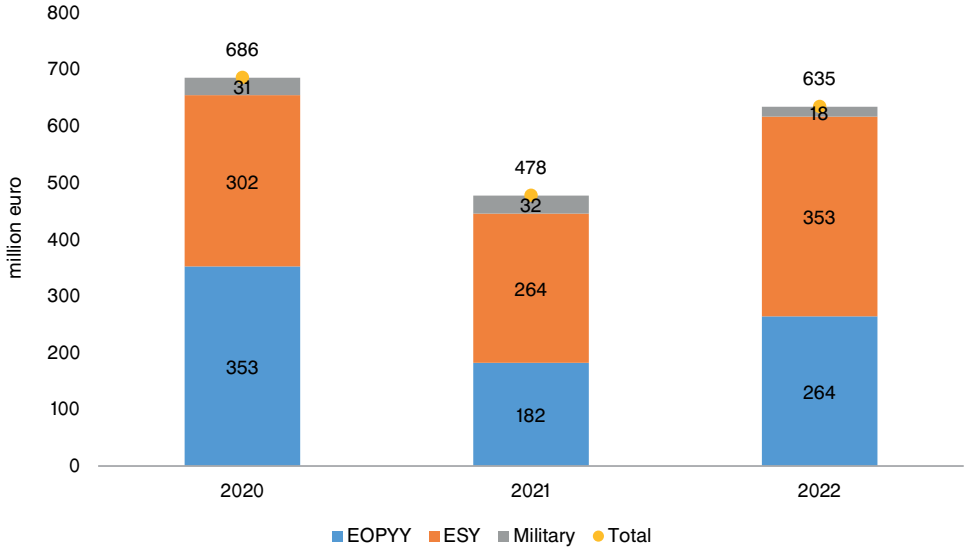
5.1 STATE'S OUTSTANDING DEBTS TOWARDS PHARMACEUTICAL COMPANIES

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 31.12.2022 only for the pharmaceutical industry are presented.

The total amount of outstanding debts presented below concerns the National Health Service, EOPYY and military hospitals, as they constitute the largest part of health expenses. Specifically, the analysis shows that: On 31.12.2022 the aggregated debts amount to **€635 million**, €264.2 million from EOPYY and **€ 353 million** from hospitals, while respectively in December 2021 it was €182.3 million for EOPYY and €295.8 million from hospitals. In conclusion the total debts increased from €478.1 million in December 2021 to €635.4 million in December 2022.

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 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 56: 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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