COUNTRY HEALTH PROFILE

THE CASE OF GREECE

1st Draft

The Impact of Underinvestment on Medicines and Health Services in Greece

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August 2022

Health is a value in itself.

- **Health/Wealth** is also a precondition for economic prosperity.
- People's **health** influences **economic outcomes** in terms of **productivity,** labor supply, human capital and public spending.
- **Investing in sustainable health systems** combines **innovative reforms** aimed at improving **cost-efficiency**.
- **Investing in people's health as human capital** helps improve the health of the population in general.
- **Investing in health helps the EU and the CEE** countries rise to the challenges identified inits Health **Strategy Europe 2025**.
- Evidence across the EU and the CEE Member States reveals the significant **underinvestment** in health and the **need for policy intervention to improve access and Health Outcomes.**

Take home messages

During the period 2010 – 2019, the Greek economy underwent an extensive overhaul in order to meet a series of predefined fiscal adjustment targets within the frame of the austerity programs designed by the ECB, IMF, and EC i.e., the Troika. The reforms introduced aimed to improve Greece's comparative advantage in the global marketplace, mainly by improving the management of its public finances. The mix of measures included extensive decreases of public spending in critical sectors such as welfare, education, and health, combined with tax increases. Although the fiscal targets were attained, the reforms had a detrimental social impact whereby the Greek economy shrank by 25%, the disposable income collapsed, while unemployment rose to a record of 25%.

The unilateral focus on the fiscal aspects of the economy impacted negatively the health and welfare system as the reduction of cost emerged as a top priority. The austerity measures created an unprecedented pressure to the financing of the Greek NHS which correlates with a notable setback of the health outcomes of the Greek population e.g., the increase of infant mortality rate from 2013 to 2020 and the decline from 2010 to 2016 of the healthy life years, in contrast with the EU-average corresponding trends; the decline of the percentage of the population reporting very good or good health in Greece.

The imperative for cost reduction led to the underfinancing of the public health sector that in turn resulted to the escalation of the unmet needs for medical care, a trend which was especially intense in the period 2010-2016. On the contrary, the unmet needs for prescribed medicines remained at relatively low level, despite the radical decrease of the public pharmaceutical expenditure over the same period.

The fiscal adjustment of the public pharmaceutical sector was set at the epicenter of the reforms regarding the Greek NHS. Indeed, between 2009 and 2015 the outpatient pharmaceutical expenditure decreased by 60.5%. This target was achieved with the implementation of policy measures that included harsh horizontal price cuts, extensive mandatory rebates and -mainly- the setting of predefined annual closed budget ceilings whereby any excesses would be returned to the State by the industry.

This approach was successful in achieving the fiscal targets regarding the pubic pharmaceutical expenditure; however, it created a non-sustainable environment especially for generics and older affordable medicines in general, whereby the combination of radical price cuts with exhausting rebates and clawbacks led to the withdrawal of more than 1,700 generics between 2014-2019. The patients treated with these generics were obliged to follow more expensive therapeutic options. However, despite the extensive price cuts, generics volume remained low due to the absence/ delays in implementation of structural measures to proper incentivize the use of generics, to control over-prescription and most importantly to control of the unnecessary/ unjustified switching to new expensive therapies i.e., binding prescription protocols, prescription guidelines, and registries as well as incentives at the pharmacy level. Notably, after a decade of pharmaceutical policy reforms, Greece still presents the lowest generics penetration among the EU countries.

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Extended Summary

Over the past five decades Greece marked a significant improvement in terms of health status and outcomes, thus converging with the rest of the EU countries. This largely came as a consequence of the vivid socioeconomic development that took place in Greece in the past five decades. The developments in Greece's economic and social life were transposed into gains and improvements in critical health indicators i.e., the increase of life expectancy, especially for women, the radical decline of infant mortality, the improvement of the self-reported health status and the increase of healthy life years. However, these positive trends seemed to contract at the decade 2009-2018, where Greece endured an unprecedented economic crisis, partly created by three adjustment programs that although stabilized the fiscal aspects of the public domain by introducing a series of much needed reforms, plunged the real economy into a deep recession which in turn created a series of negative social implications.

The crisis era was characterized by the radical decrease of the financing of the health sector, following pre-determined fiscal targets e.g., the total pharmaceutical expenditure per capita decreased by 26%, the public spending per capita for pharmaceuticals and other medical goods, decreased by 52%, and the overall public pharmaceutical expenditure decreased by ~60%. The fiscal targets were successfully met; however, this was achieved through a series of horizontal measures that apart from being largely ineffective in rationalizing the health care system, were also proved unsustainable at the medium turn. The unilateral focus over the fiscal aspects of the health system, mainly through supply-side measures towards the health care (and pharmaceutical) providers, created little room for the design and implementation of the so muc needed structural measures that would create a sustainable environment for the NHS, the health care providers and -more importantly- the patients. It is worth-noted that e.g., private pharmaceutical expenditure per capita in Greece increased by 65% during the crisis period where the incomes collapsed. This is of great importance especially within the frame of the general income collapse that was evident during the crisis. The increase of the private pharmaceutical expenditure, could be attributed to the reduction of the public pharmaceutical financing which fostered a substitution effect towards private expenditure. The austerity measures implemented especially after 2012 led to the creation of an extraordinary burden for the Greek households which was largely reflected in the reported increase of the unmet medical needs. Unfortunately, the measures implemented fell short to form a coherent policy in order to address the perennial distortions that plagued the Greek NHS: a highly-fragmented, hospital-oriented system with limited economic efficiency and accountability, characterized by unjustified over-consumption of pharmaceuticals and medical goods, absence of medical prescribing monitoring and control, with poor administrative capacity, with the lack of the necessary data to support informed, evidence-based decision making etc.

The cost containment measures imposed within the frame of the fiscal adjustment programs fueled an unpresented economic recession for over a decade, which in turn triggered a series of

negative societal implications. The formula adopted for the health sector, hindered the patients' access to health and pharmaceutical care, compromised the viability and sustainability of the Greek NHS, increased the uncertainty in the health-care sector and therefore resulted to a long period of under-investment or even disinvestment both for the public and the private sector. However, the new landscape regarding the healthcare in EU, emerging at the aftermath of the coronavirus crisis, creates a significant opportunity for an overall update of the health and pharmaceutical sector in Greece as well as for the rest EU countries.

1. The objectives of this study

The objectives of this study were to assess the impact of underinvestment on medicines and health services in Greece by reviewing data on health outcomes, expenditures, and unmet medical needs of the Greek population, and comparing them against the European Union average (EU-27).

In terms of methodology, our analysis is based mainly on Eurostat data, complemented by data from OECD, and the National Statistical Office in Greece. This provided an evidence-based framework for the preparation of the report, and in case that the findings needed for more elaboration and explanation additional -evidence were sought. Additionally, we describe the Greek health care system background and the pharmaceutical policies implemented in Greece, providing the information needed to understand our findings.

2. Country background

Greece is a Southeast European country with a population of 10.8 million, a low fertility rate (1.3) and a high proportion of elderly population (21.3% of total population. Furthermore, in 2016 (?) the GDP per capita in nominal terms was estimated at €16,154 and the unemployment rate at 23.6% [18]. Regarding population health, Greece follows the epidemiological profile and health trends of the Southeast European Countries. Life expectancy at birth was 81.5 years in 2015 (83.7 and 78.5 years for women and men, respectively), higher than the respective average estimate in the European Union (EU) [19]. The principal causes of death in 2014 were cardiovascular diseases (43% of deaths among women and 36% among men), cancer (20% among women and 30% among men) and respiratory conditions (11% for both women and men) [19]. Furthermore, a notable increase has been observed in the recent years in infant mortality from 2.7 in 2008 to 3.7 deaths per 1,000 live births in 2015, and in suicide rates from 3.3% to 4.8% per 100,000 in the period 2008-2014 [19]. Finally, the overall adverse effect of the economic crisis on the health status of the Greek population is also evident in Health-Related Quality of Life metrics, such as the EuroQol instrument. The decline in mean EQ-VAS scores, i.e. from 86.1 in the pre-crisis period to 76.7 in 2015, indicate a significant deterioration of subjective health in the recent years [1].

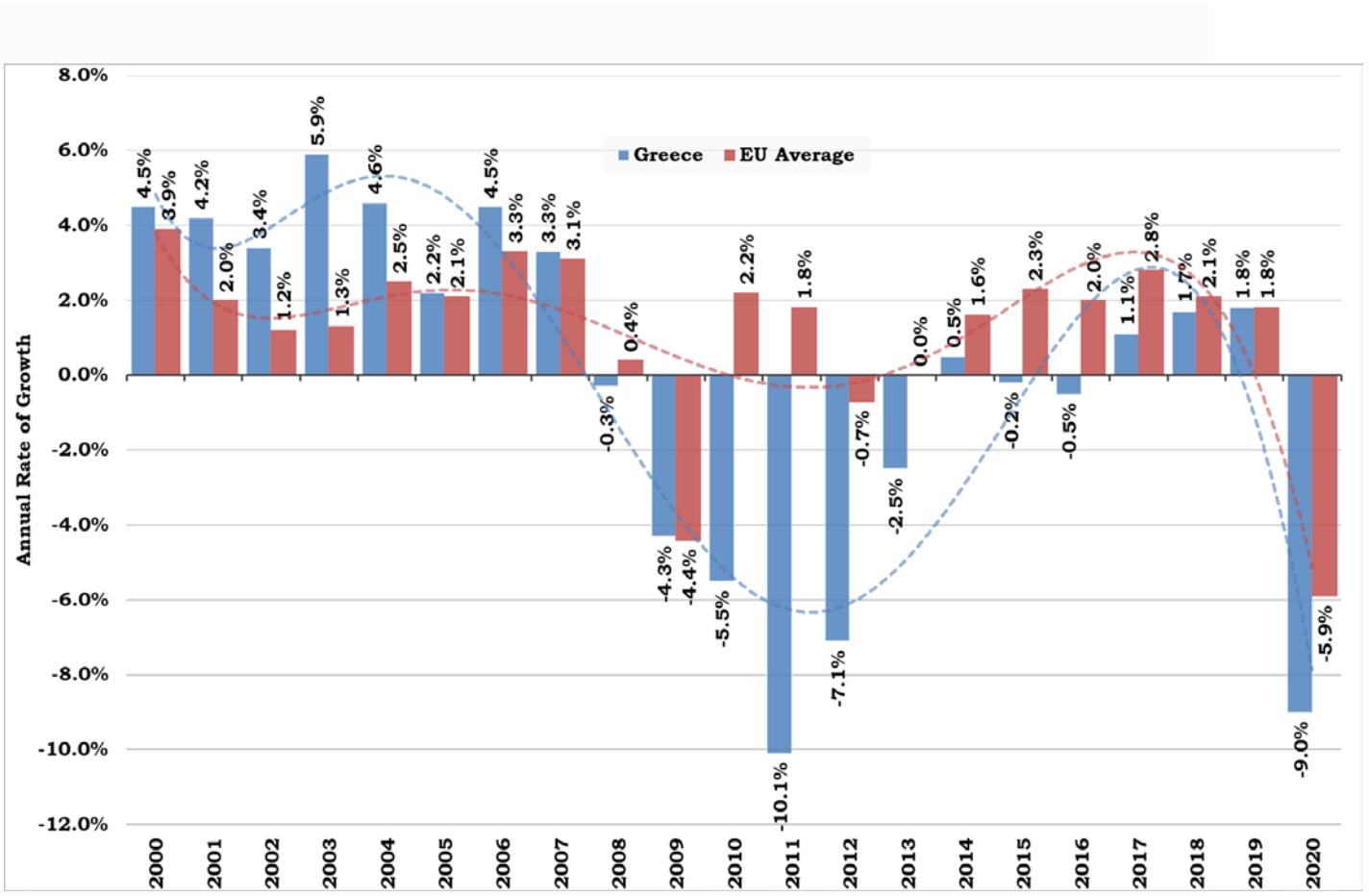
After a decade of recession followed by the COVID-19 pandemic, the Greek health system nowadays faces significant social, economic and health challenges. After three consecutive economic adjustment programmes, and several reforms focusing mainly on harsh funding cutbacks, the social goals of the European health model should be reconsidered and redefined. The negative effects of the crisis on society, economy and health should be viewed as a “window opportunity” to rethink the European core values and to implement the relevant health policies in an effective and efficient way.

2.1 Economic Cycles

After a decade (2000–2008) of flourishing economic growth, fluctuating annually around the level of 4% (whereas the corresponding EU-27 average was at around 2% at that time), the Greek economy went into recession in 2009. (See Figure 1). The economic downturn resulted to a series of economic and social adverse effects with a direct negative impacting for the health sector. More specifically, in 2009 the first signs of the economic crisis were evident with an initial decrease of GDP at -4.3%, followed by a new decrease of -5.5% in 2010. In 2011, the recession extended to a much greater degree than what was initially expected for the Greek economy. GDP shrank by -10.1% percentage points, a unique value deterioration among the EU countries. The first sign of recovery was observed in 2012 whereby the GDP decreased at a slower pace -7.1%, followed by -2.5% in 2013. However, over the period 2015-2016, the recession continued despite the expectations for recovery. No economic forecast specified the ‘depth', i.e., the magnitude of the GDP reduction and the duration of the economic crisis. Especially regarding the economic crisis duration, it is worth noted that although it lasted seven years, its social repercussions are still present, representing the longest crisis among the EU countries. Over the 2008–2015 period, GDP was reduced by 29.5%, wages were reduced by 35–45%, private consumption dropped by 30% and public health expenditure declined by 41%. Over the same period income inequality (S80/S20) increased by 11%, the unemployment rate reached 27.1% (marking an increase of 276.4%) and consecutively, the share of population at risk of poverty increased from 27.6% in 2009 to 36% in 2014.

The overall period of recession lasted a decade in Greece, from 2008 to 2018, with a slight recovery in 2019. However, the COVID-19 crisis triggered to a new global recession which had a negative impact resulting to the reduction of GDP by -9.0 in 2020. Figure 1 portrays the “depth” and the “duration” of the “Greek economic tragedy” with the most noticeable recession in 2011 and 2020, year of the COVID-19 outbreak.

Figure 1 Quarterly evolution of GDP in Greece 1996-2020



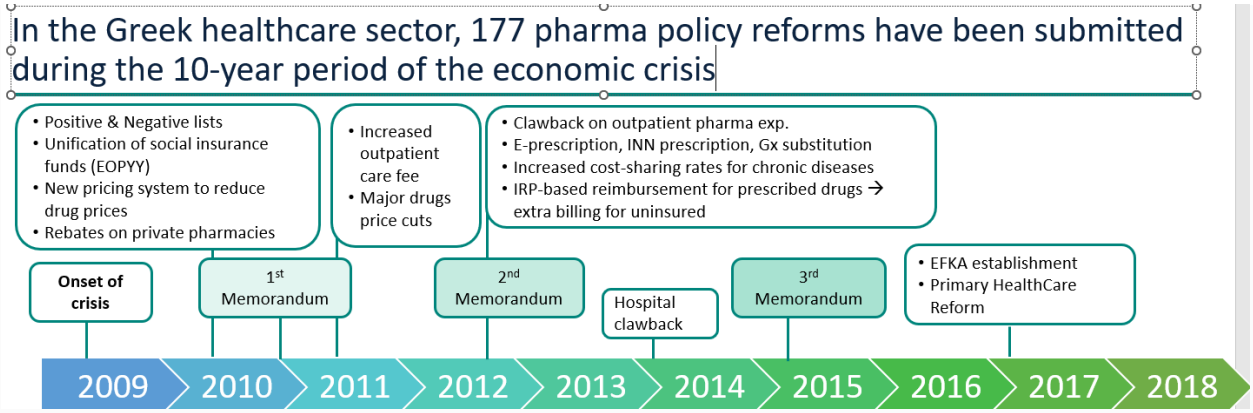
Source: National Statical Service of Greece

2.2 Rescue package and conditions

The Greek government has signed three bailout Economic Adjustment Programmes with the European Union institutions in 2010, 2012, and 2015. (see Figure 2) The Eurozone countries and the IMF provided three rescue packages to Greece [10,11,12] The main purpose of these packages was to improve growth, competitiveness and investment opportunities. The first Economic Adjustment Program was signed in May 2010 between Greece and Troika (European Commission, European Central Bank, International Monetary Fund), and the total amount of financial assistance was €110 billion. The second Economic Adjustment Program, which added up to €130 billion, was signed in February 2012, while and the third program was agreed in June 2015, and it amounted to €86 billion. The signed terms of these bailouts included a series of conditionalities in the form of prerequired reforms such as liberalization of several protected economic and employment sectors, the severe reduction of public expenditure, the fight against corruption and underground economy, and the implementation of three austerity packages. In the

welfare sector a plethora of measures has been implemented to curtail social and health expenditures and to improve the efficiency and effectiveness of the welfare system and the health/pharmaceutical sector.

Figure 2: 2009 – 2018: A period of reforms



Source: YFANTOPOULOS 2021

3. The Health System in Greece.

The health system in Greece presents the features of the Southern European model based on the mixture of (a) insurance-based principles in the finance and delivery of health services (Bismark -German model), and (b) the universality in coverage, access and utilization of services (Beveridge model). Health care is provided by a three-party system i.e., the public sector (National Health Service-NHS), the Social Security Funds-SSFs and the private sector. The Ministry of Health and Social Solidarity is responsible for the overall organization, financing and delivery of health services. Prior to 2010 the health system in Greece was fragmented with an overlapping of services, high administrative cost and lack of incentives for economic efficiency and equity in the delivery of services. There were four major Social Security Funds (IKA, OGA, OAEE and OPAD) covering 95% of the Greek population. After the adoption of the First Economic Adjustment Programme and the passage of Laws 3863/2010 and 3918/2011, efforts were undertaken by the Greek government to streamline the different insurance schemes by pooling the health risks under a unified system, harmonizing the benefit packages and merging the insurance funds into a single health insurance fund i.e., EOPYY -The National Organization for the Provision of Health Services. EOPPY started its operation as a single buyer of health care services in June 2011 and since 2016 covers the total population of Greece, including the uninsured. In March 2012, the passage of Law 4052/2012 introduced a new impetus in the reorganization and restructuring of the Greek National Health Service System (NHS) aiming at reducing inefficiencies, promoting economies of scale and scope, improving the quality of services, and ensuring greater access to health services. Over the period of the last five years new policies were introduced in hospitals by implementing a DRG System, in the primary care, the diagnostics, and the pharmaceutical sector.

3.1 European Health Consumer Index – a tool for European countries health care systems comparison[1]

European Health Consumer Index (EHCI) is a composite index used to assess the performance of national healthcare systems in 35 countries. The EHCI analyses national healthcare on 46 indicators, with the use of a unified questionnaire, looking into areas such as Patient Rights and Information, Access to Care, Treatment Outcomes, Range and Reach of Services, Prevention, and use of Pharmaceuticals.

The details of methodology are Subject to changes that are reported in every EHCI report. It should be noted that the EHCI methodology has been criticized by experts from the European Observatory on Health Systems and Policies[2] for that:

[1] https://healthpowerhouse.com/publications/ (access 19.08.2022)
[2] Cylus J, Nolte E, Figueras J, McKee. M. What, if anything, does the EuroHealth Consumer Index actually tell us? theBMJOpinion

- The index is constructed by scoring performance as good, intermediary or not-so-good, based on arbitrary cut-off points.
- There is no logic in how many points are allocated to each indicator, e.g., 225 points are allocated to accessibility, but only 250 to health outcomes.
- The indicators are a mix of trends over time and cross-sectional rankings.

2018 EHCI report is the last one available, so no assessment of health care systems during the COVID-19 pandemic has been performed according to EHCI methodology. However, assessments of health care systems performance in specific fields that are available as: European Diabetes Index of 2014 and European Heart Index of 2016.

The results of the assessment are produced in terms of scores for every one of six indicators (partial scores) as well as the total score (sum of partial scores). Scores are marked at the map of Europe with three colors: green for the best scores (the highest), amber for the intermediate ones (the middle scores) and red for the not-so-good systems (lower scores). In the 2018 EHCI report there is a statement, that the green countries on the map are scoring >750 on the 1000-point scale, while red – scoring <650; the minimum possible score is 333 (see Figure 1)

https://blogs.bmj.com/bmj/2016/02/09/what-if-anything-does-the-eurohealth-consumer-index-actually-tell-us/ (aaccessed 27.08.2022)

Figure 1. Health systems performance according to EHCI in 2014 and 2018

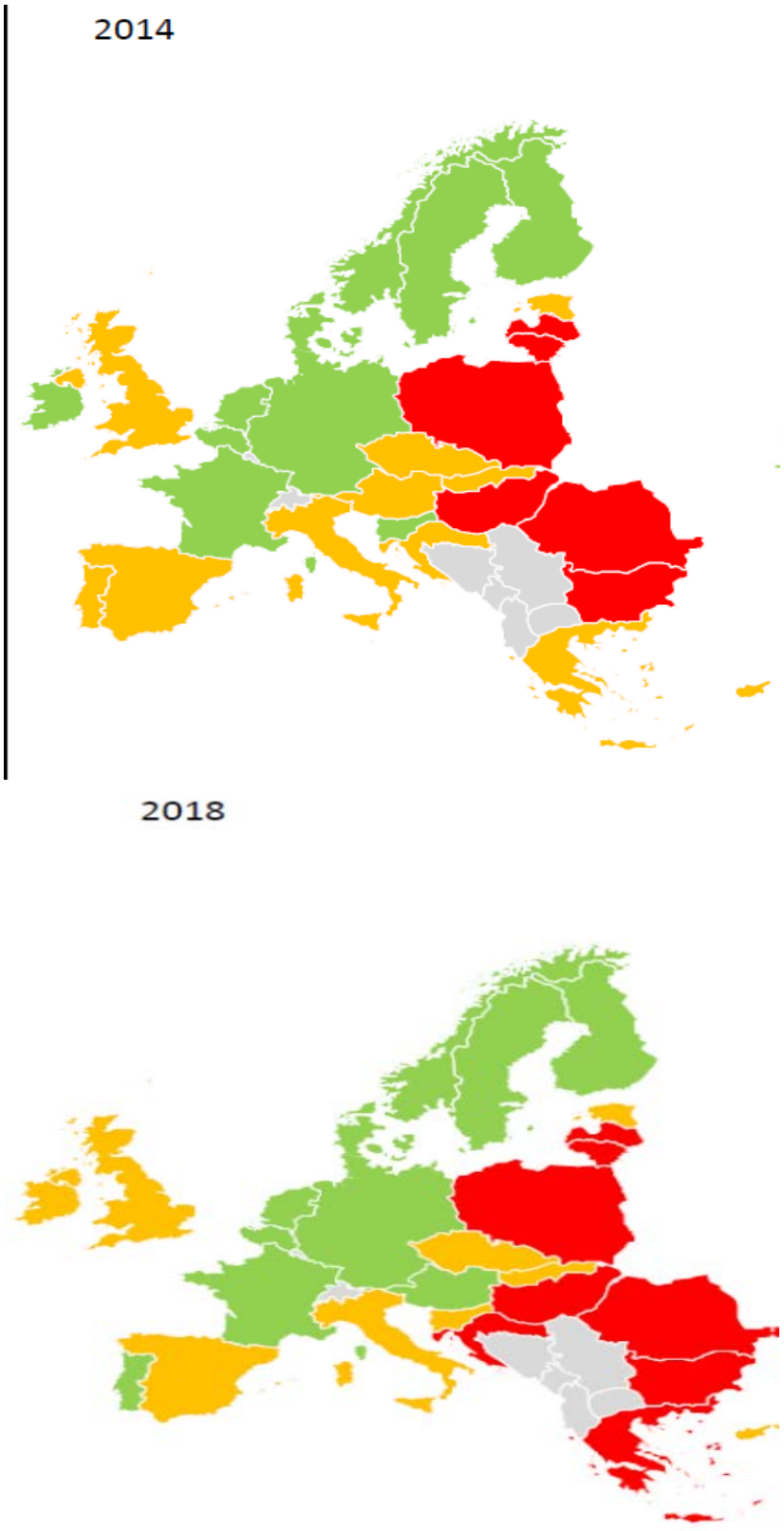
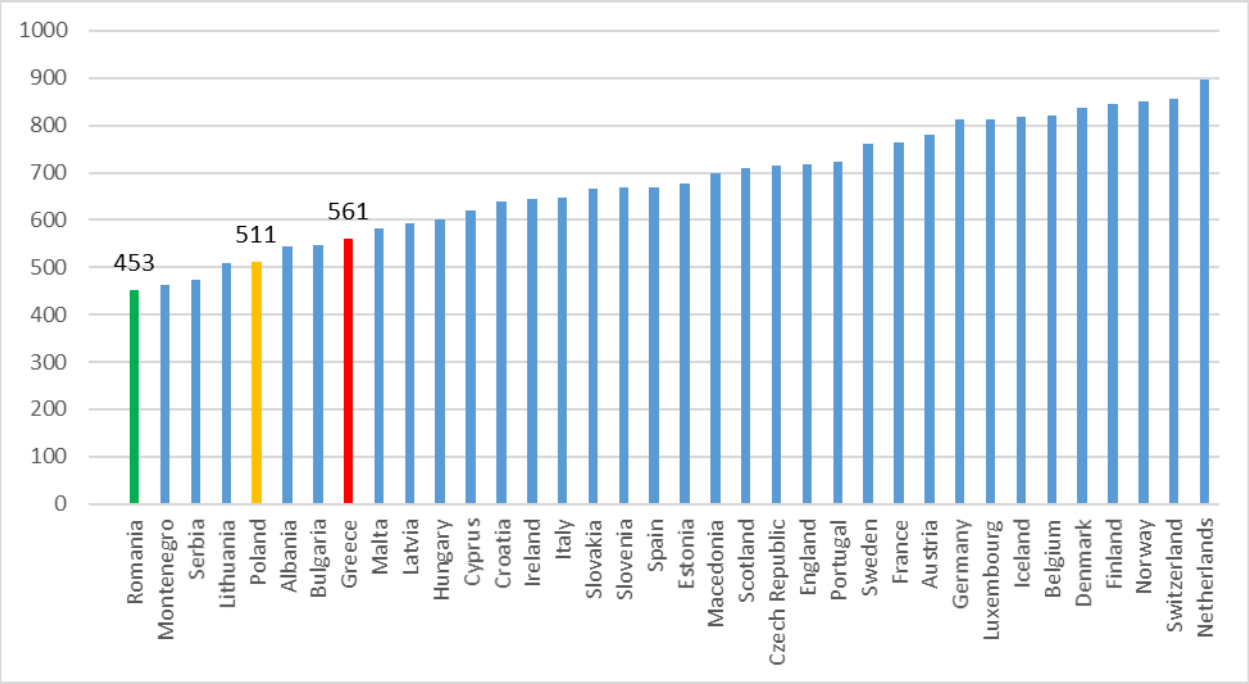
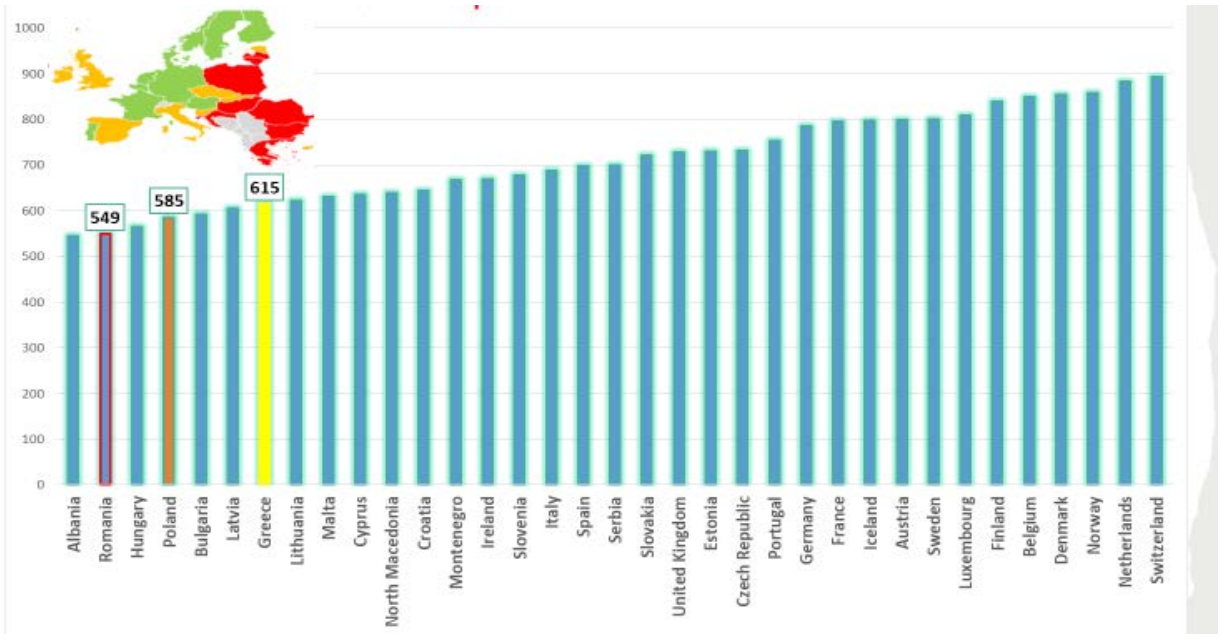


Figure 3: Total score European Health Consumer Index in 2014



Source:

Figure 4: Total score European Health Consumer Index in 2018



Source

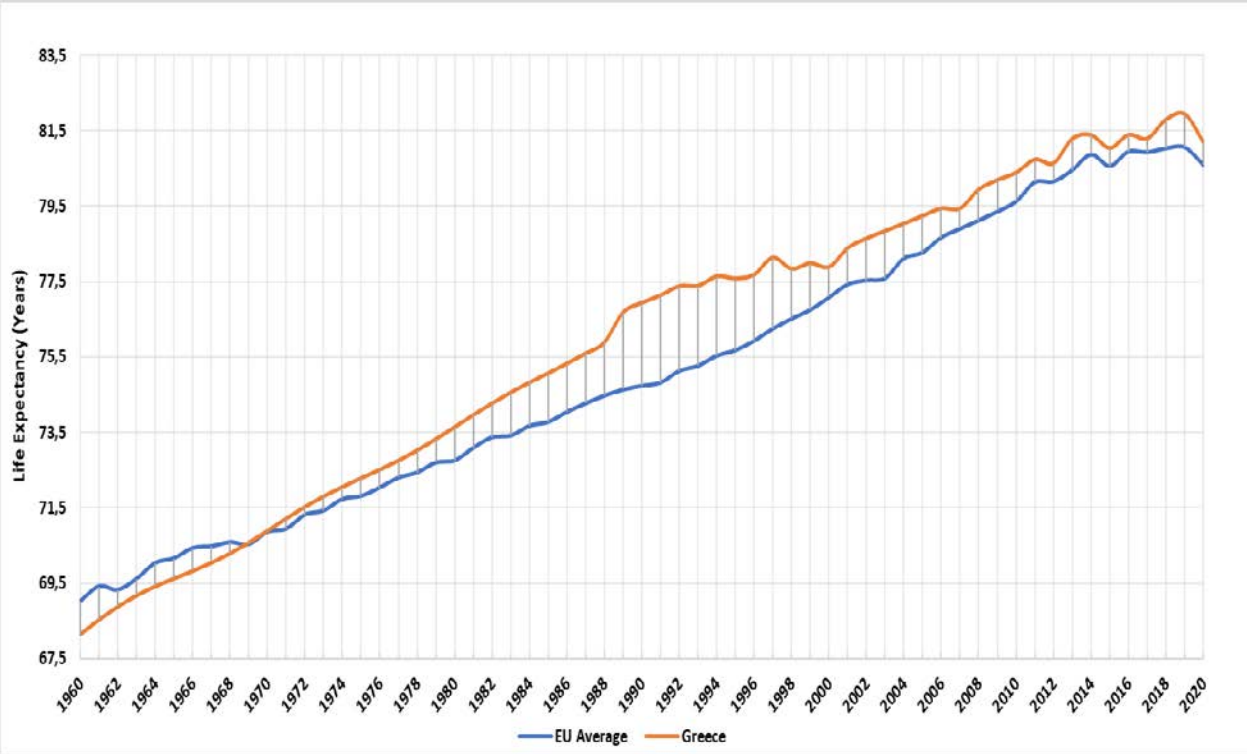
4. Trends in Health Outcomes.

Over the past five decades, and throughout the pre-crisis period life expectancy and health status have increased steadily in Greece following the rest of the European Countries. The gain in life expectancy since 1950's, in the EU-27 countries is estimated to be around 10 years on average. Similar improvements in longevity and health status have been recorded in Greece, since the 1950's reaching the level of 77.2 years for men and 82 years for women for 2006 in the pre-crisis period. Infant mortality has declined significantly over time in Greece from 43.52 infant deaths (per 1,000 live births) in 1955, to 3.7 per 1,000 live births) in 2006. The main causes of death in 2006 were cardiovascular diseases accounting 30% of total deaths, neoplasms (24.6%), cerebrovascular (16.4%) and respiratory diseases (7.8%). The health gains observed in Greece over the past four decades are mainly attributed to improvements in living conditions, Mediterranean diet, improved access to health services and pharmaceutical care. This argument is supported by several health interview surveys conducted by the Health Economics research unit at the University of Athens and other academic institutions.

4.1 Life expectancy at birth

Figure 5 displays the changes in life expectancy at birth over time in Greece and in Europe overall. Life expectancy has increased in both the EU and Greece over the past 50 years, but this progress has slowed down over the last decade. Life expectancy at birth reached its peak point in 2019 for both Greece (81.93 years) and EU (81.06 years). Although between 1960 and 1966, life expectancy at birth in Greece was lower related to the EU average, from 1967 and onwards the comparison was always favorable for Greece, which steadily presented a higher life expectancy at birth compared with the EU average, a difference that was more intense in the period 1989-1999, whereby the gap reported ranged from 1.23 to 2.32 years. However, after 2000, the gap between the EU average and Greece narrowed, a trend that was more intense after 2014. In 2020, the COVID-19 pandemic led to the decrease of life expectancy in Greece, a decline that reached almost 1 year, in comparison with the previous year.

Figure 5. Life expectancy at birth in the EU and Greece (1960- 2020)



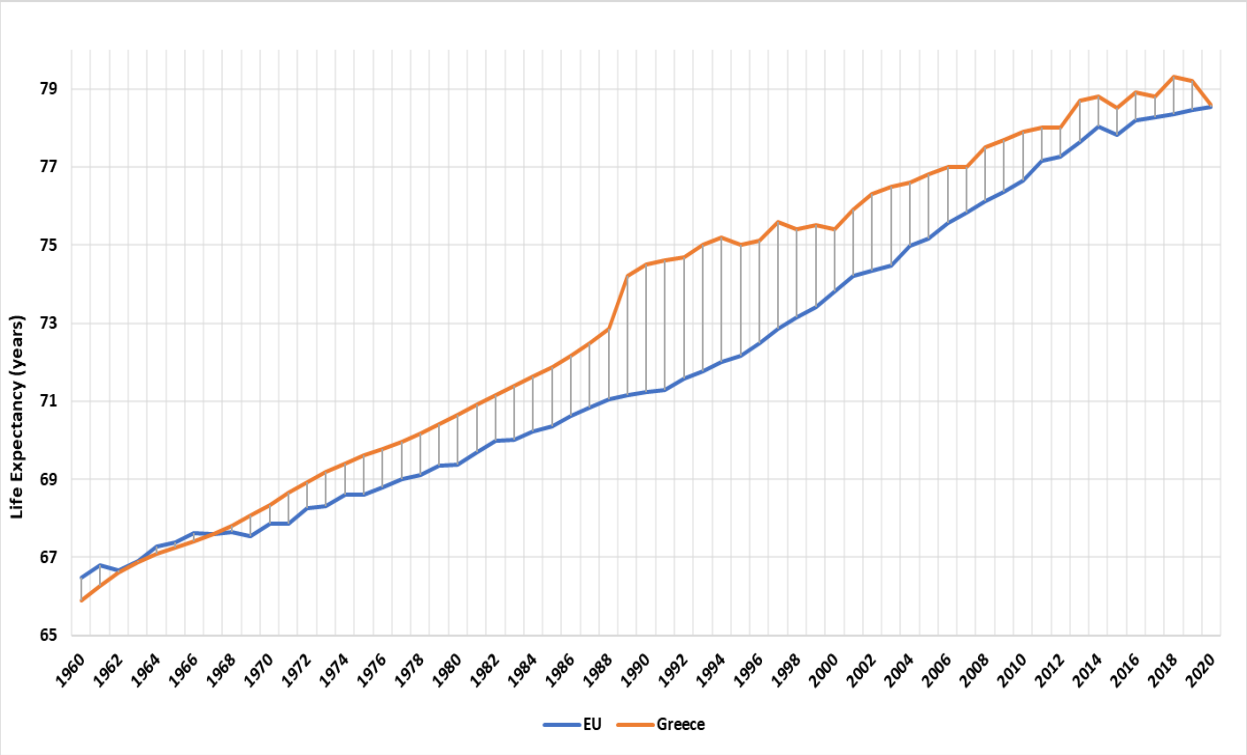
Source: World Bank Health database, accessed August 2022

4.2 Life expectancy by sex

Women live longer than men in both Greece and the EU with the gender gap averaging 5.5 years in Greece and 6.5 years in the EU. Regarding the male life expectancy at birth, it reached its peak in 2020 (78.54 years) across the EU and in 2018 (79.3 years), refer to Greece. The highest female life expectancy at birth was reported in 2018 not only in the EU (83.86 years), but also in Greece (84.4 years).

Figure 6 displays the changes occurred in male life expectancy in the EU and in Greece. Although from 1960 to 1967 the male life expectancy was higher across the EU compared with Greece, from 1968 and onwards, life expectancy was higher in Greece. From 1970 until the latest year of data available (2020), life expectancy is steadily increasing, with the exception of the year 2019, when a decline of nearly 1 year was shown in Greece. The biggest gap between the EU and Greece was reported at the period 1989-1999, whereby the difference varied from 2.08 years to 3.31 years. After the year 2000, the gap became narrower, in particular from 2014 and onwards.

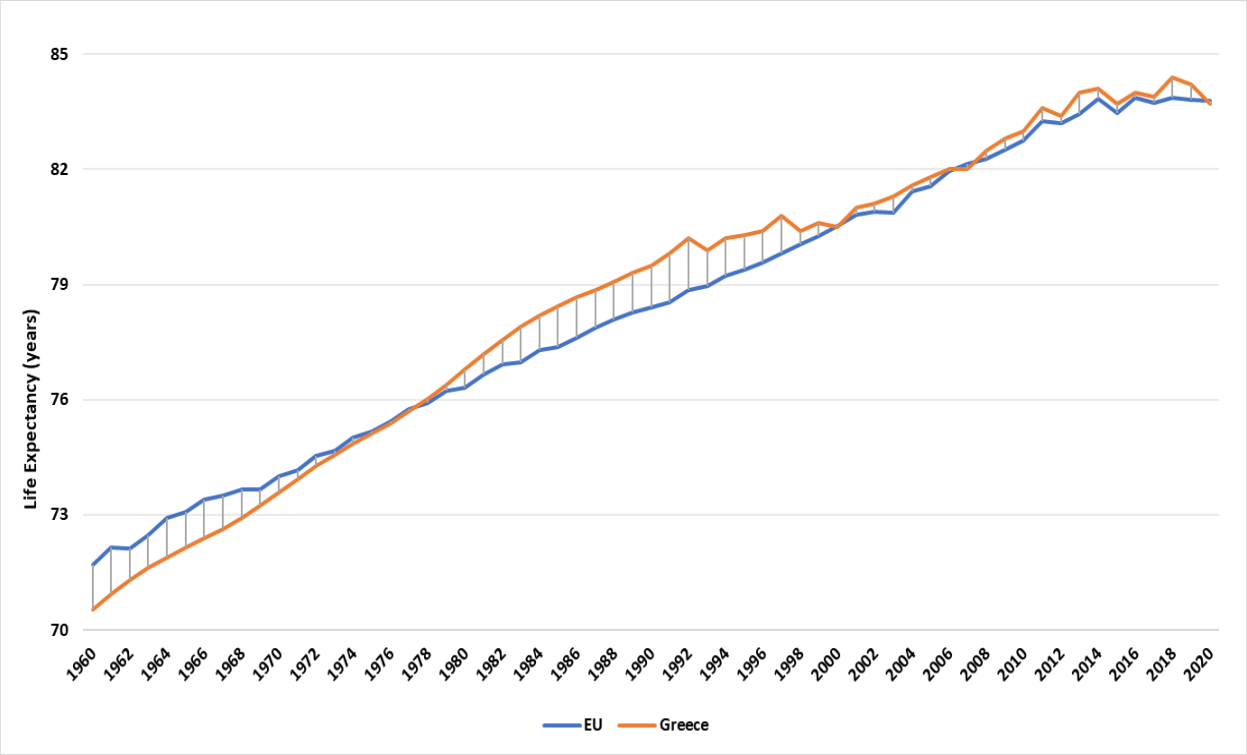
Figure 6. Male life expectancy at birth in the EU and Greece (1960- 2020)



Source: World Bank Health database, accessed August 2022

As presented in Figure 7, from 1960 to 1977 female life expectancy at birth was higher in the EU compared with Greece, although the gap was steadily decreasing. From 1978 and onwards, life expectancy was higher in Greece, although no significant difference to the female expectancy in the EU was noted. During the past 4 decades, the only gap noticed between the EU and Greece was reported for the period 1978-1999, with Greece presenting a higher than EU average life expectancy that ranged from 0.11 to 1.33 years.

Figure 7. Female life expectancy in the EU and Greece (1960- 2020)



Source: World Bank Health database, accessed August 2022

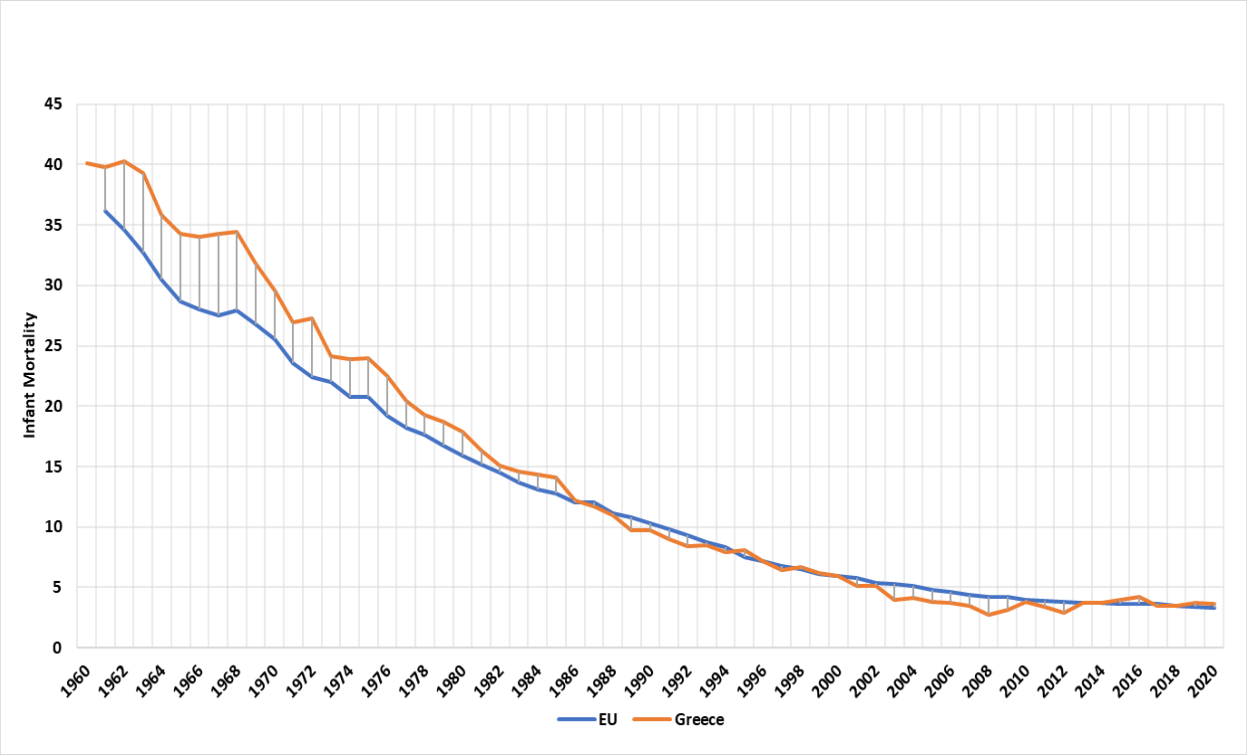
During the period 1960 – 2020, life expectancy at birth for men in Greece increased by 12.7 years, while the corresponding gain for the EU was 12.07 years. On the other hand, female life expectancy at birth increased by 13.16 years in Greece and by 12.09 in the EU. In conclusion, there was no gender gap regarding the life expectancy gained in the EU. However, women in Greece gained approximately half a year more than the Greek men.

4.3 Infant mortality rate

Infant mortality rate in the EU and Greece marked a decreasing trend from 1960 to 2013, which was followed by an opposite trend considering Greece. Overall, infant mortality rate decreased from 40.1 deaths to 3.6 deaths per 1,000 live births in Greece between 1960 and 2020, which translates to a decline of 91%. Infant mortality rate decreased also in the EU from 36.2 deaths to 3.3 deaths per 1,000 live births between 1961 and 2020, which translates to a decline of 90%. Examining the period 1960- 1986, infant mortality was higher in Greece than in the EU average. The gap averaged to 4 deaths per 1,000 live births. From 1987 to 2012, infant mortality rate in the EU and Greece were converged. However, from 2013 to 2020 infant mortality rate in Greece became higher than the correspondent one in the EU, which continued to decrease thereafter.

This finding implies that the positive trend for Greece was reversed most probably due to the economic crisis.

Figure 8. Infant mortality rate in the EU and Greece, 1960- 2020 (deaths per 1,000 live births)

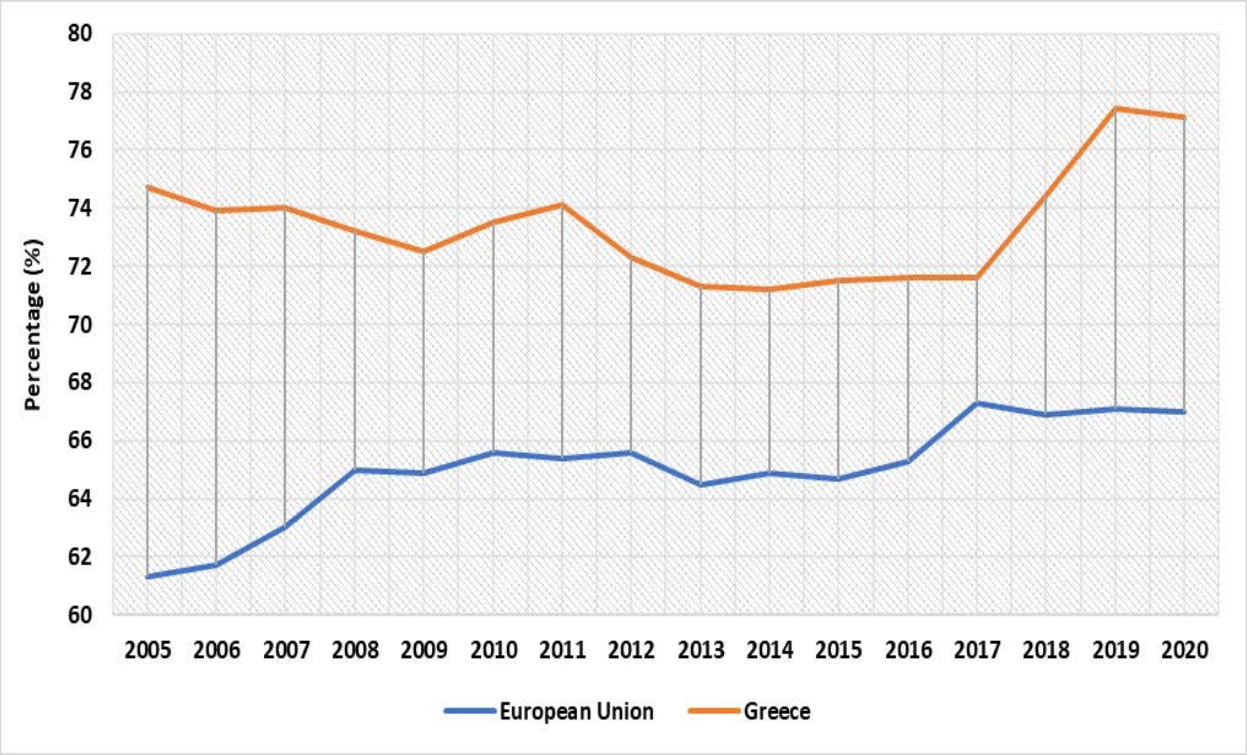


Source: World Bank Health database, accessed August 2022

4.4 Percentage (%) of men reporting very good or good health (2005-2020)

Figure 9 shows the changes in men's self-reporting health status during the period 2005- 2020. All over this period, the share of men reporting very good or good health was significantly higher in Greece than in the EU. The gap between Greece and the EU average decreased by 4.3 percentage points (pp) (from 13.4 pp in 2005 to 9.1 pp in 2020). The disparity was wider at the period 2005 -2007 (approx.12 pp). From 2008 to 2018 the difference shrank, followed by a surprising sharp increase up to 2020, where a decrease of 0.5 pp was noted in the EU and of 1.3% in Greece.

Figure 9. Percentage (%) of males reporting very good or good health 2005-2020

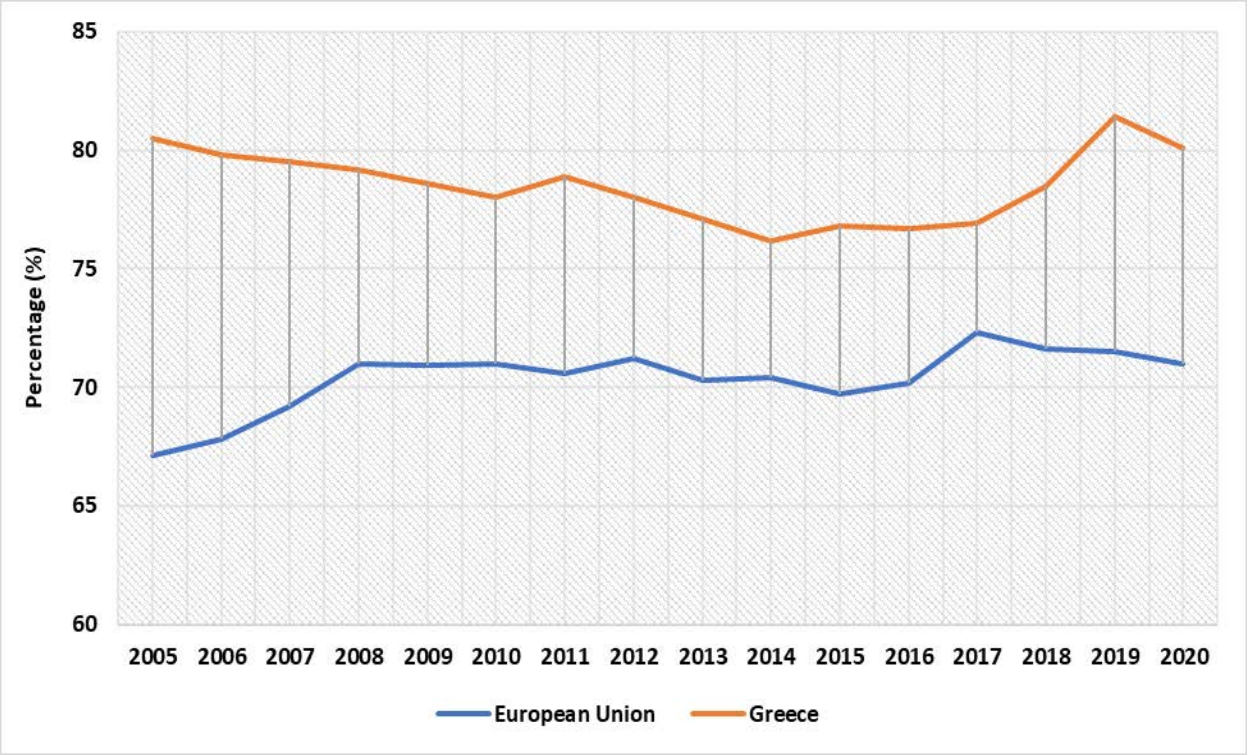


Source: Eurostat, accessed August 2022

4.5 Percentage (%) of women reporting very good or good health

During the period 2005-2020, the share of women reporting very good or good health, was always higher in Greece than in the EU. The gap between Greece and the EU average, decreased by 3.3 pp from 13.4 pp in 2005 to 10.1pp in 2020. From 2012 to 2016 the disparity between Greece and the EU remained rather stable at approximately 6.6 pp. From 2017 and onwards, there a sharp increase of the percentage of the Greek women that reported very good or good health was marked, while at the same time a slight decrease was observed in the corresponding EU average.

Figure 10. Percentage (%) of females reporting very good or good health2005-2020

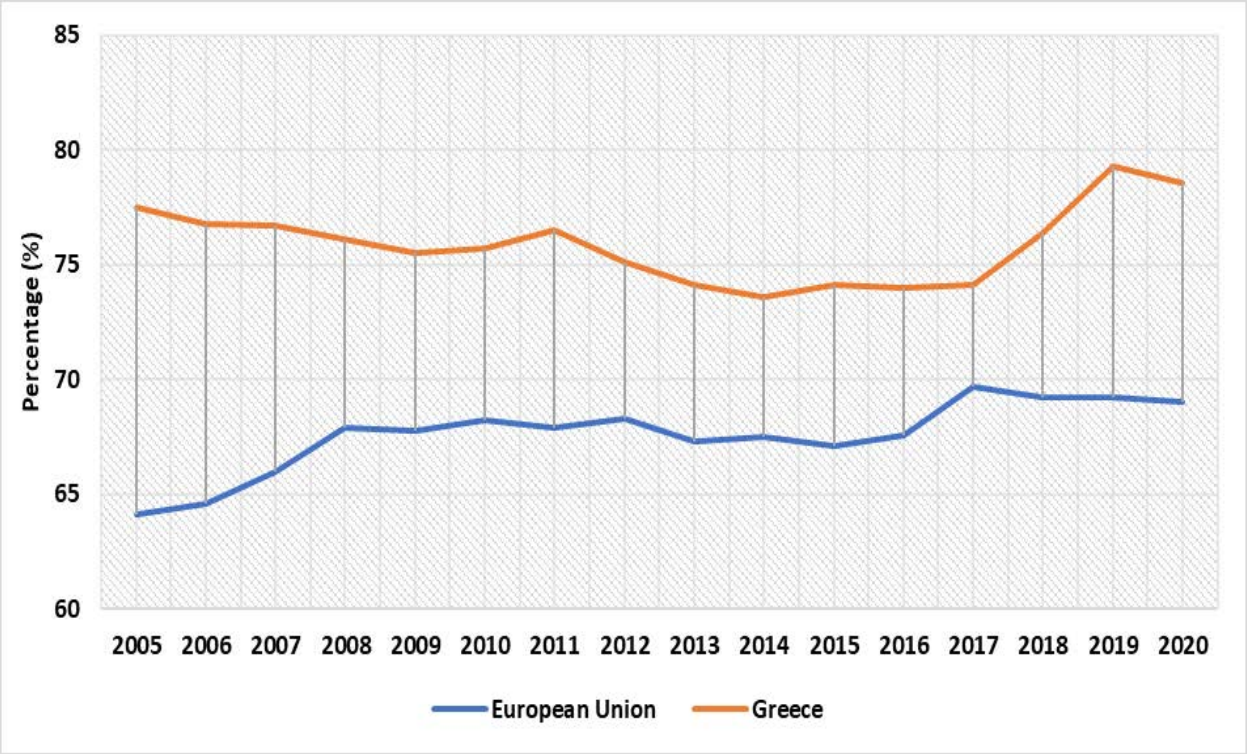


Source: Eurostat, accessed August 2022

4.6 Percentage (%) of total population reporting very good to good health

As described on Figure 11, during 2005-2020, the share of the population reporting very good or good health was significantly higher in Greece than in the EU. The gap between Greece and the EU average decreased from 13.4 pp in 2005 to 9.6 pp in 2020. From 2012 to 2014 the disparity between Greece and the EU remained rather stable at 6.56 pp. From 2015 to 2019, there was a sharp increase in the Greek men and women reporting very good or good health, and a corresponding slight increase regarding the EU average. In 2020, a slight decrease was found both for Greece and the EU.

Figure 11. Percentage (%) of total population reporting very good or good health



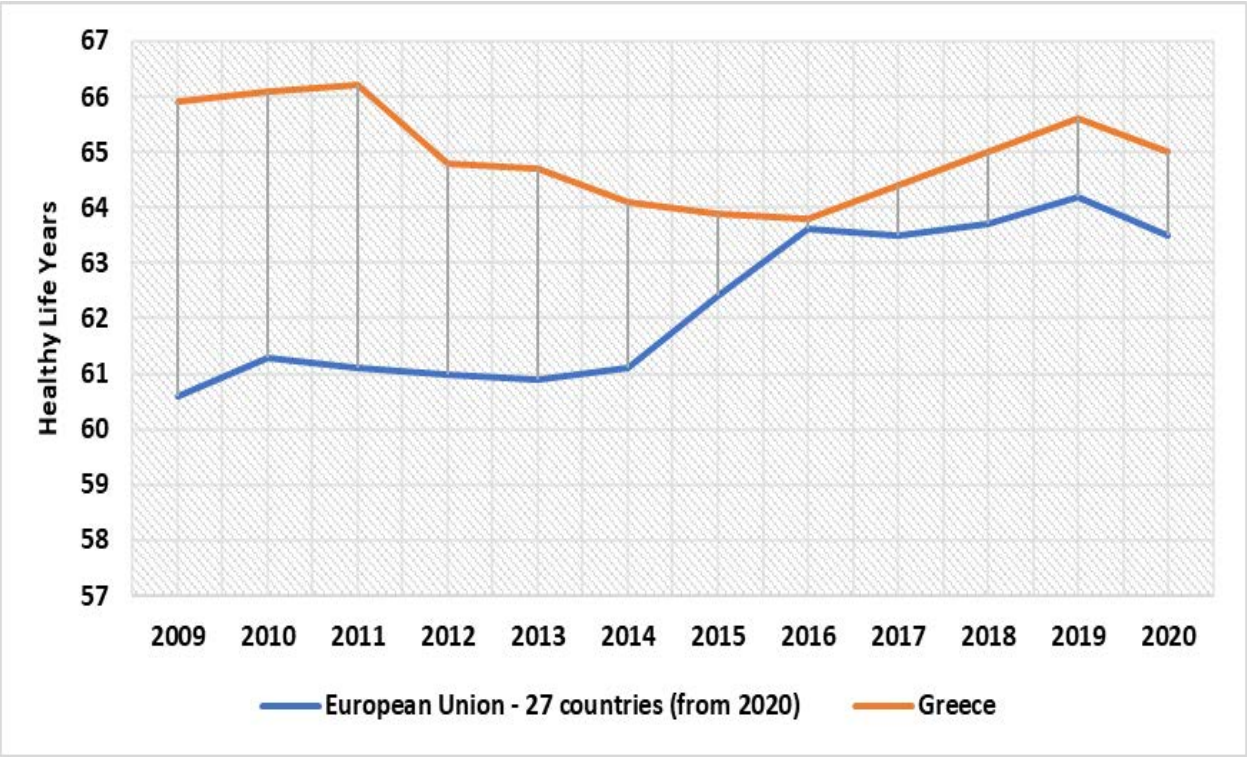
Source: Eurostat, accessed August 2022

4.7 Healthy life years among men in Greece and the EU (2009-2020)

In 2020, the healthy life years in the EU was 63.5 years for men and 64.5 years for women, while in Greece was 65 years for men and 66.8 years for women.

Concerning men, healthy life years have always been found to be higher in Greece that in the EU. The existing gap decreased from 5.3 years in 2009 to 1.5 years in 2020. In 2016 healthy life years among men in Greece were as high as those in the EU (approximately 63.7 years). From 2016 healthy life years increased both for Greece and in the EU, but the trend was more intense for Greece in particular. It should be also mentioned that the negative health impact of the pandemic is evident in the estimates of this measure as well in 2020.

Figure 12. Healthy life years among men in Greece and the EU (2009-2020)

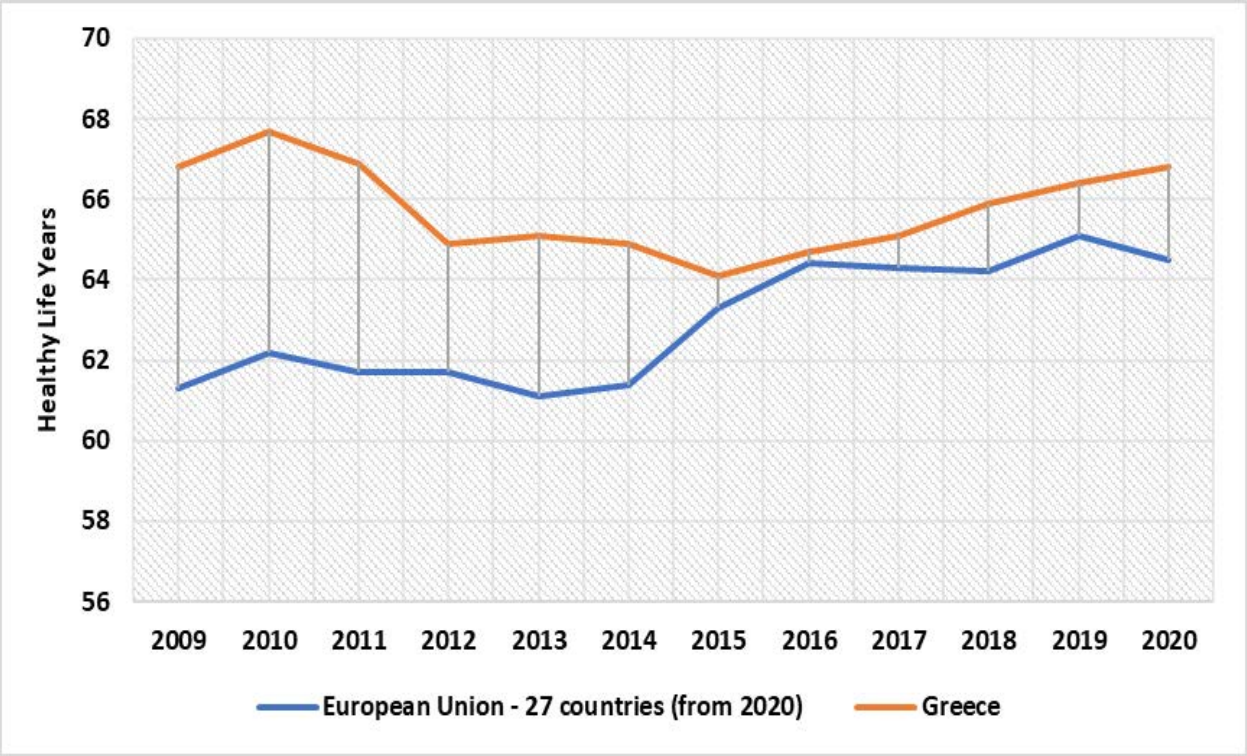


Source: Eurostat, accessed August 2022

4.8 Healthy life years among women in Greece and the EU (2009-2020)

As shown on Figure 13, the existing gap of 5.5 years in 2009 concluded in a gap of 2.3 years in 2020. Healthy life years among women reached its highest point in Greece in 2010 (67.7 years) and in the EU in 2019 (65.1 years). In 2016, almost total convergence is achieved at approximately 64.55 years. After this point, healthy life years among women in Greece are steading increasing, even after the onset of COVID-19 pandemic, while, on the other hand, healthy life years in the EU remain somewhat stable, with only exception in 2019, when a slight increase by 0.9 years is noted.

Figure 13. Healthy life years among women in Greece and the EU (2009-2020)

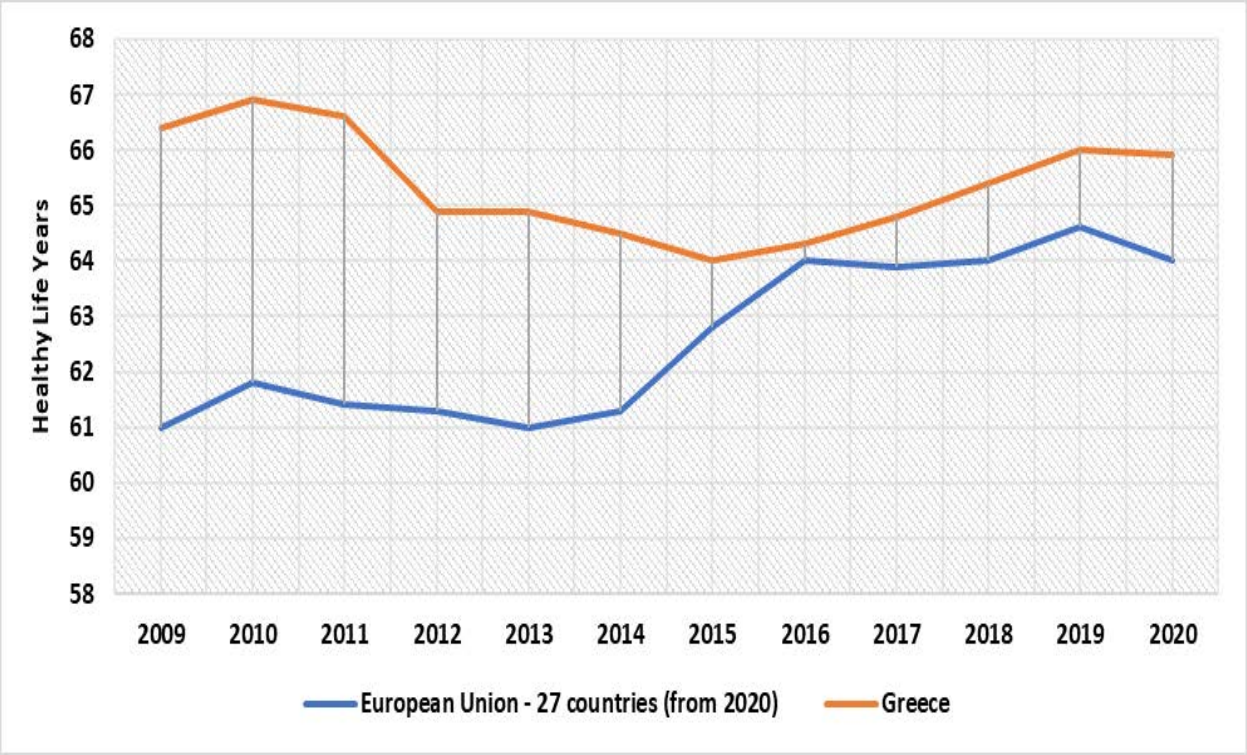


Source: Eurostat, accessed August 2022

4.9 Healthy life years in total in Greece and the EU (2009-2020)

Figure 14 shows the changes in healthy life years in total in both Greece and the EU. The gap between the EU and Greece decreased from 5.4 years in 2009 to 1.9 years in 2020. From 2012 to 2017 convergence of the existing gap is observed, followed by divergence in the year after 2019.

Figure 14. Healthy life years in total in Greece and the EU (2009-2020)



Source: Eurostat, accessed August 2022

4.10 Health outcome - main conclusions

Over the past five decades Greece marked a significant improvement in terms of health status and outcomes following the rest of the EU countries. This is largely attributed to the socioeconomic development that took place in Greece during the post-World War II era. The improvements in living conditions, the improved access to health services and pharmaceutical care, the Mediterranean diet, have been recognized as main contributors to this positive trend.

Live expectancy at birth has increased in both the EU and Greece over the past 50 years. From the 60s decade and onwards Greece scored better than the EU average presenting a higher life expectancy at birth, a trend that peaked in the period 1989-1999. However, after 2000, the gap between the EU average and Greece narrowed as the progress slowed down especially over the past decade.

Although women tend to live longer than men in both Greece and the EU have been no significant differences on the evolution of the life expectancy by sex between men and women in Greece compared with the EU average.

Infant mortality rate in Greece between 1960 and 2020, declined by 91%. The decline was similar for both Greece and the EU up to 2013 whereby Greece followed an opposite increasing trend, a finding that could be attributed to the economic crisis which negatively affected the timely access to effective health care.

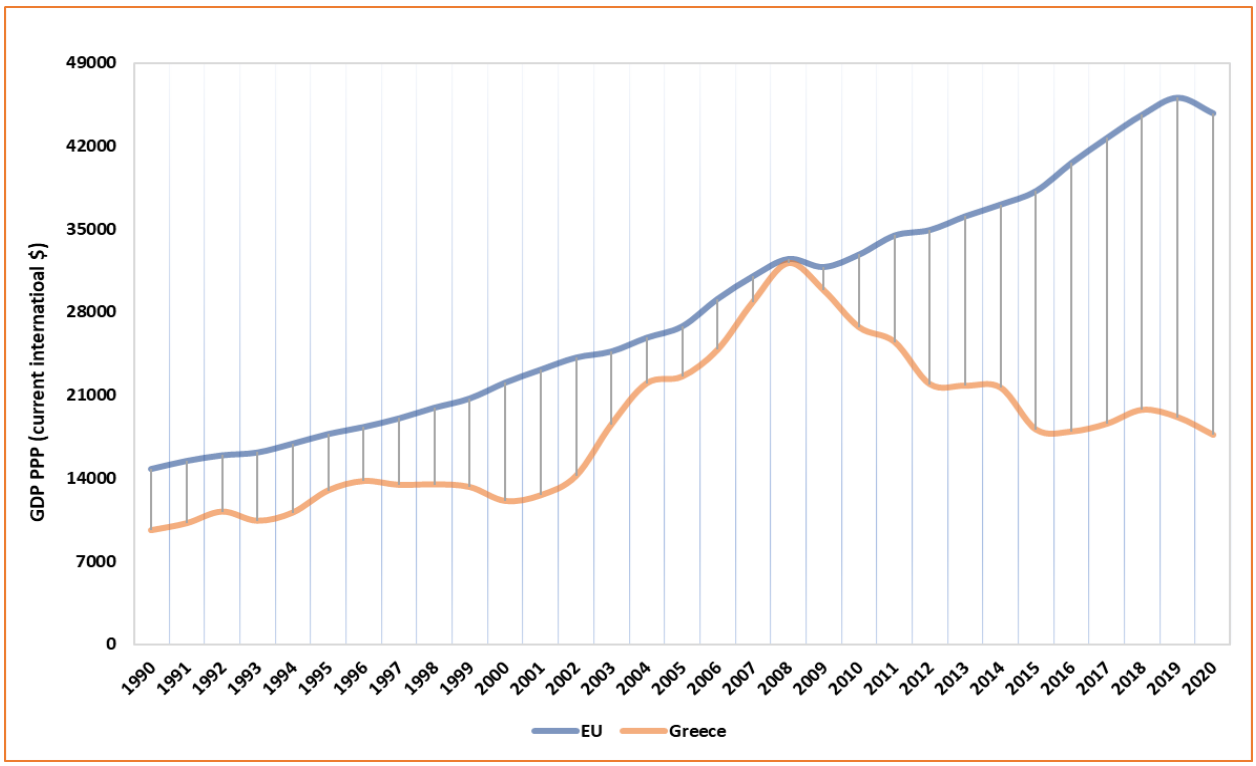
All over the period 2005-2020, the share of men reporting very good or good health was significantly higher in Greece than in the EU. However, the gap between Greece and the EU average decreased overtime, a trend that became more intense at the period 2008-2018. The trend was similar for women, although from 2017 and onwards a sharp increase of the percentage of the Greek women that reported very good or good health was marked, while at the same time a slight decrease was observed regarding the corresponding EU average. This pattern applies for the total population as well.

Greeks scored slightly better than the EU in terms of healthy life years through out the whole period examined, however the gap decreased from 5.3 years in 2009 to 1.5 years in 2020. This same gap-decreasing trend was observed for women whereby in 2016 almost a total convergence between Greece and the EU was reported.

5. GDP per capita

Figure 15 shows the changes of GDP per capita in the EU and in Greece between 1990 and 2020. In order to come into a conclusion, one should separate the years examined into two different periods; the first from 1990 to 2008 and the second one from 2009 to 2020. The point of interception was 2009, during which the onset of the economic crisis is placed. As for the first period, a continuous increase in GDP per capita considering the EU is noticed, which reached the highest point at 2009 (46,069 $). On the other hand, GDP per capita in Greece not only was significantly lower than the corresponding EU average but also, the increase of GDP in the decade 1990-1999, was followed by an opposite trend in the period 2000-2002, expanding the existing gap with the EU. From 2003 and onwards, an upward trend was observed, which led to convergence with GDP per capita of the EU. As for the second period, an intensifying divergence between the EU and Greece was monitored, since the GDP of Greece was continuously decreasing, while the corresponding EU average was increasing, reaching its highest point in 2019 (44,763 $).

Figure 15. GDP per capita



Source: Eurostat, accessed August 2022

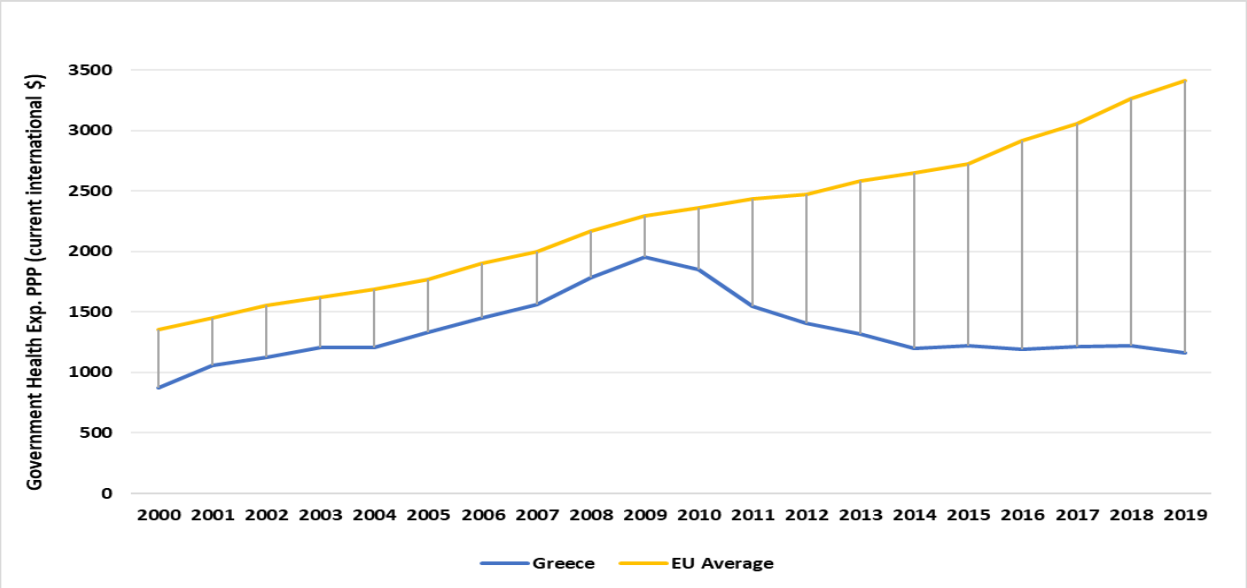
6. Health expenditure in Greece

Greece spent 9.5% of GDP on health in 2009 However, this a figure was reduced to 7.8% in 2019. However, the declining rates should be interpreted in the context of drastically shrinking GDP. Per capita spending has also fallen from 2,841US$ in 2008 to 1,501 US $ in 2019[3] a 47% reduction that puts Greece significantly below the EU average.

6.1 Public health expenditure per capita

Public health spending per capita increased in Greece, from 874 $ in 2000 to 1164 $ in 2019, registering a relative growth of 33%. Examining the evolution of public health expenditure in Greece we should distinguish two periods referring to: i) convergence from 2000 to 2009 followed by a period of ii) extreme divergence in 2009 to 2019. Greece registered an impressive increase of 124% in public health expenditure (from 874 $ to 1955$) between 2000-2009. On the onset of the economic crisis and the implementation of three austerity programmes, during 2009 to 2019 public health expenditures decreased significantly from 1955$ in 2009 to 1164 in 2019 i.e reduction by 41%. During this period Greece witnessed the highest divergence from the EU-27 Average (See figure 16). Overall, combining Figures 15 and 16, we may reach the conclusion of high convergent trends between Greece and the EU-27 before the crisis of 2009 followed by high divergent trends in the economy and the public health sector.

Figure 16. Public health expenditure per capita



[3] (World Bank (Greece Healthcare Spending 2000-2022. www.macrotrends.net. Retrieved 2022-09-13.)

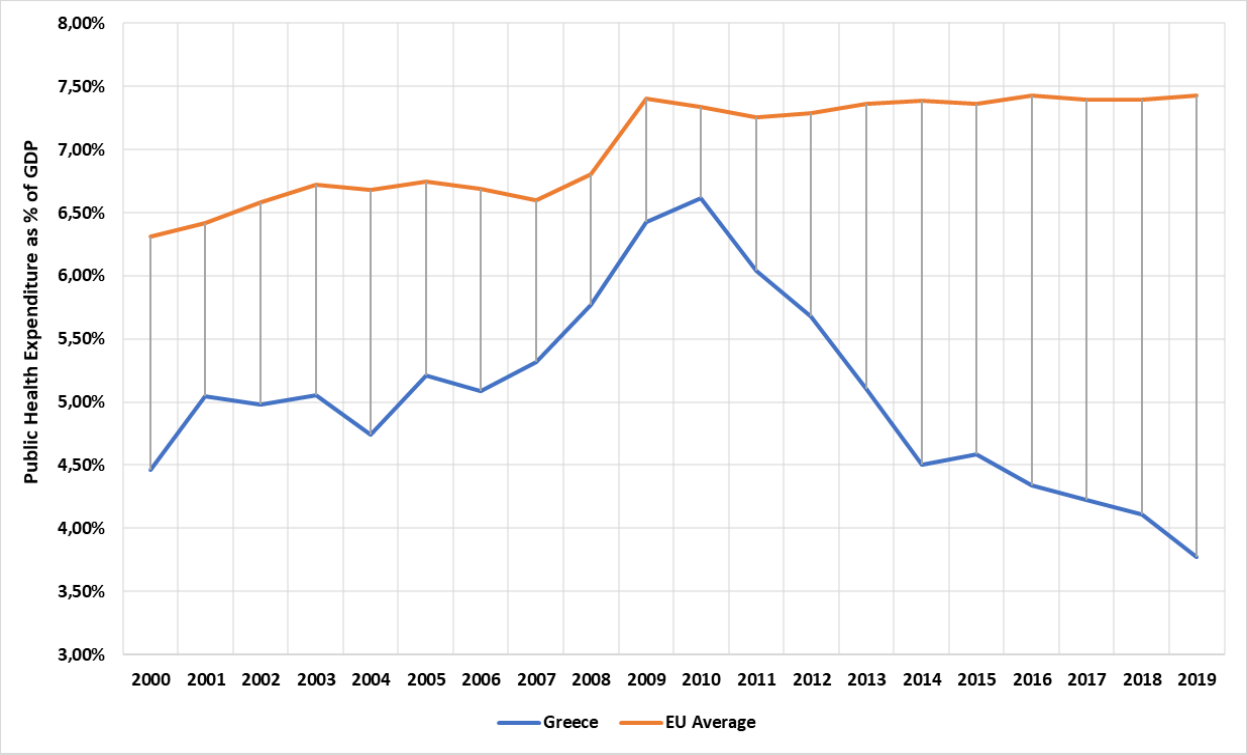
Source: Eurostat, accessed August 2022

6.2 Public health expenditure (% of GDP)

As shown in Figure 17, Europe increased its public health expenditure (% of GDP) from 6.31% to 7.43% (total increase of 1.12 pp), between 2008-2010, a period burdened by the up-coming economic crisis. On the other hand, public health expenditure in Greece was found below the European average during the whole period (2000-2019). Public health expenditure as share of GDP in Greece increased from 4.46% to 5.77% (total increase 1.31 pp) during the pre-crisis period (2000-2008). From 2009 to 2010 Greece increased its public health expenditure as much as 0.85 pp, reaching the highest % of GDP during all years examined. From 2010 onward public health expenditure significantly declined from 6,61% to 3,77% (-2.84 pp), while the over decline from 2000 to 2019 was -0.69 pp.

Especially in period 2010-2019 the gap between EU and Greece expanded at its most.

Figure 17. Public health expenditure (% of GDP)



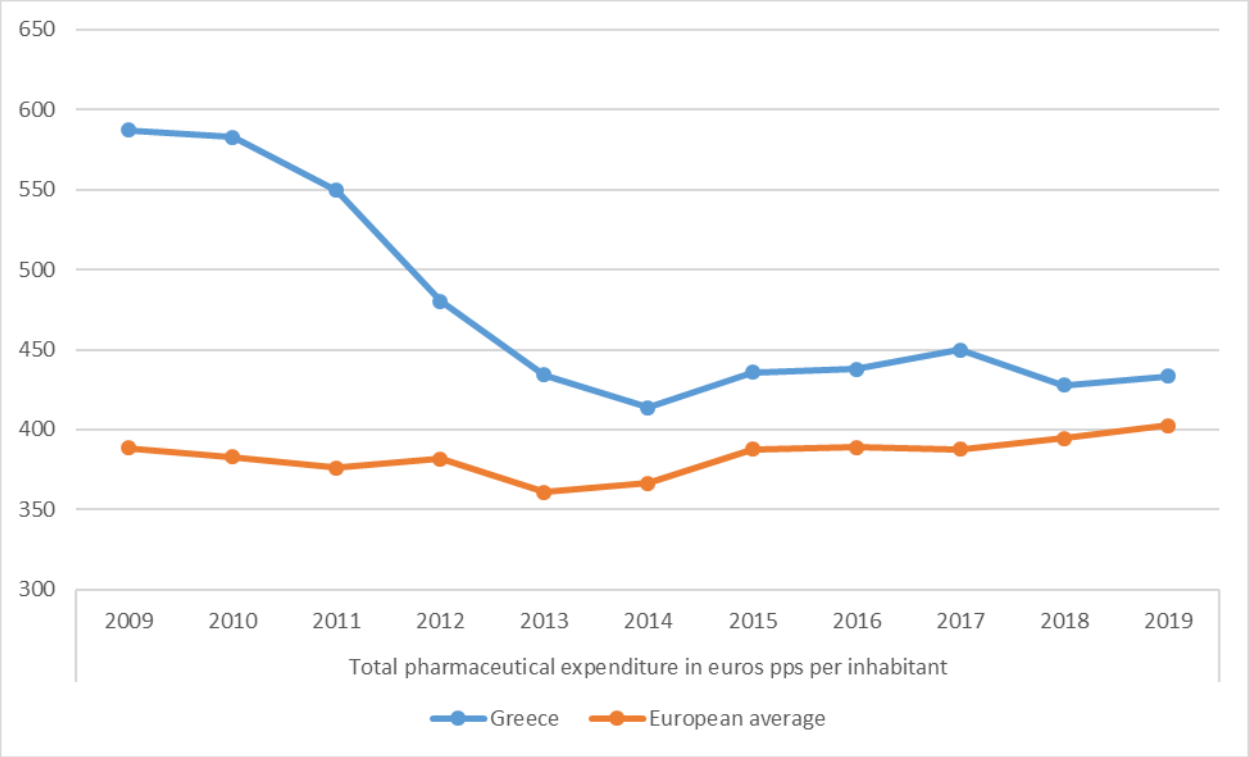
Source: Eurostat, accessed August 2022

7. Pharmaceutical Expenditure[4]

7.1 Total pharmaceutical expenditure in euros pps[5] per capita

Pharmaceutical spending covers expenditure on prescription medicines and self-medication apart from those consumed in hospitals and other health care services. Total pharmaceutical spending in our analysis refers in net costs and is measured as per capita expenditure and covers the period of 11 years. As shown in Figure 18, total pharmaceutical expenditure per capita in Greece between 2009 and 2019 decreased by 26%, from €587.37 in 2009 to €433.54 in 2019. During this period, the corresponding EU average trend increased by 3.6%, from €388.62 in 2009 to €402.69. in 2019. As is shown in Figure 18 the gap between EU and Greece was reduced significantly.

Figure 18. Total pharmaceutical expenditure in euros pps per capita



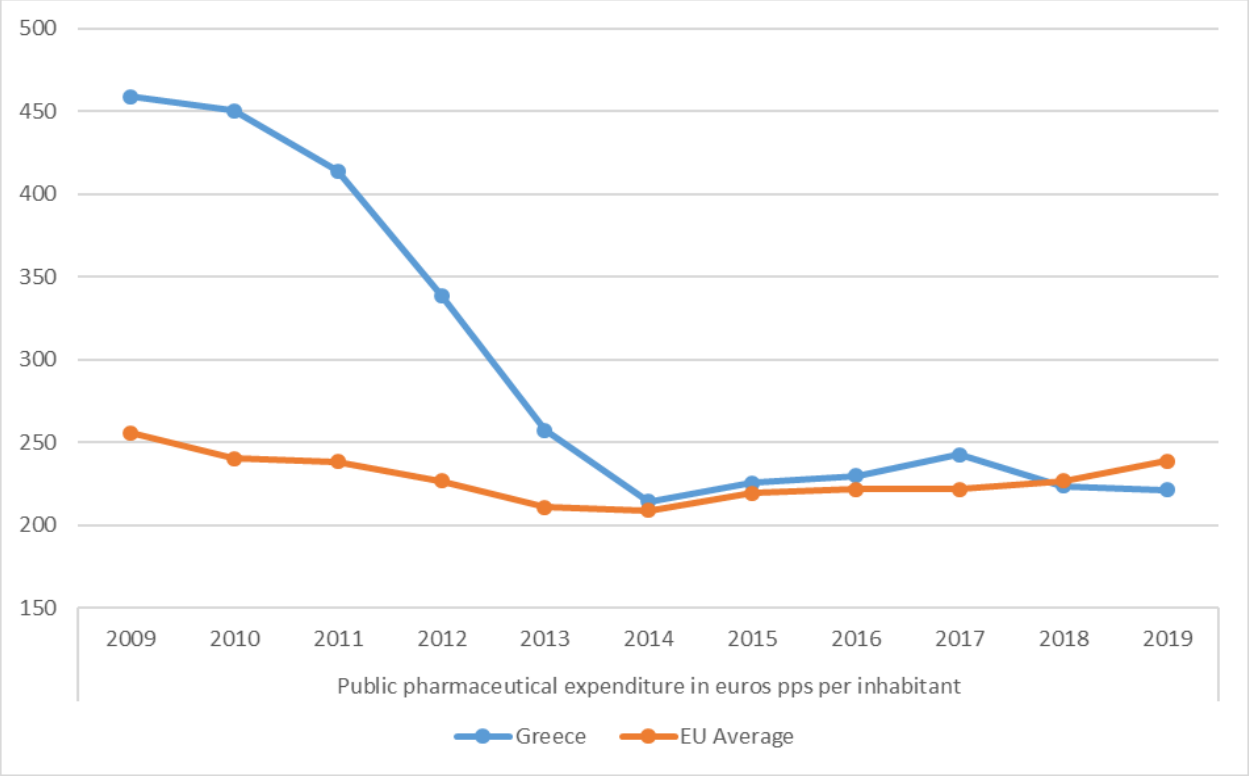
Source: Eurostat, accessed August 2022

[4] Eurostat Data (access 15.08.2022).
[5] the artificial currency unit in which the PPPs and real final expenditures for the EU 25 are expressed – namely, euros based on the EU 25. For more see https://stats.oecd.org/glossary/detail.asp?ID=7184

7.2 Public pharmaceutical expenditure in euros pps per capita

Public spending per capita for pharmaceuticals and other medical goods in Greece, decreased significantly, by -52% from €458.94 in 2009 to €221.3 in 2019 The corresponding EU average trend also presented a decrease by 6.8%, from €255.93 in 2009 to €238.67 in 2019. As shown in Figure 19, public pharmaceutical expenditure in Greece registered a significant decrease between 2009-2014 in compliance with the Economic Adjustment Programs dictated by the European Commission, the European Bank, and the IMF i.e., the Troika. After 2014 and up to 2019, Greece succeeded in implementing effective measures i.e., price cuts, mandatory rebates, and a closed budget and clawback system aiming at cost containment These measures resulted to a significant reduction of the public pharmaceutical expenditure in Greece, closing the gap between Greece and the EU average. The period 2014 - 2019 is characterized as fully convergent period with similar trends between Greece and the EU average.

Figure 19. Public pharmaceutical expenditure in euros pps per capita.



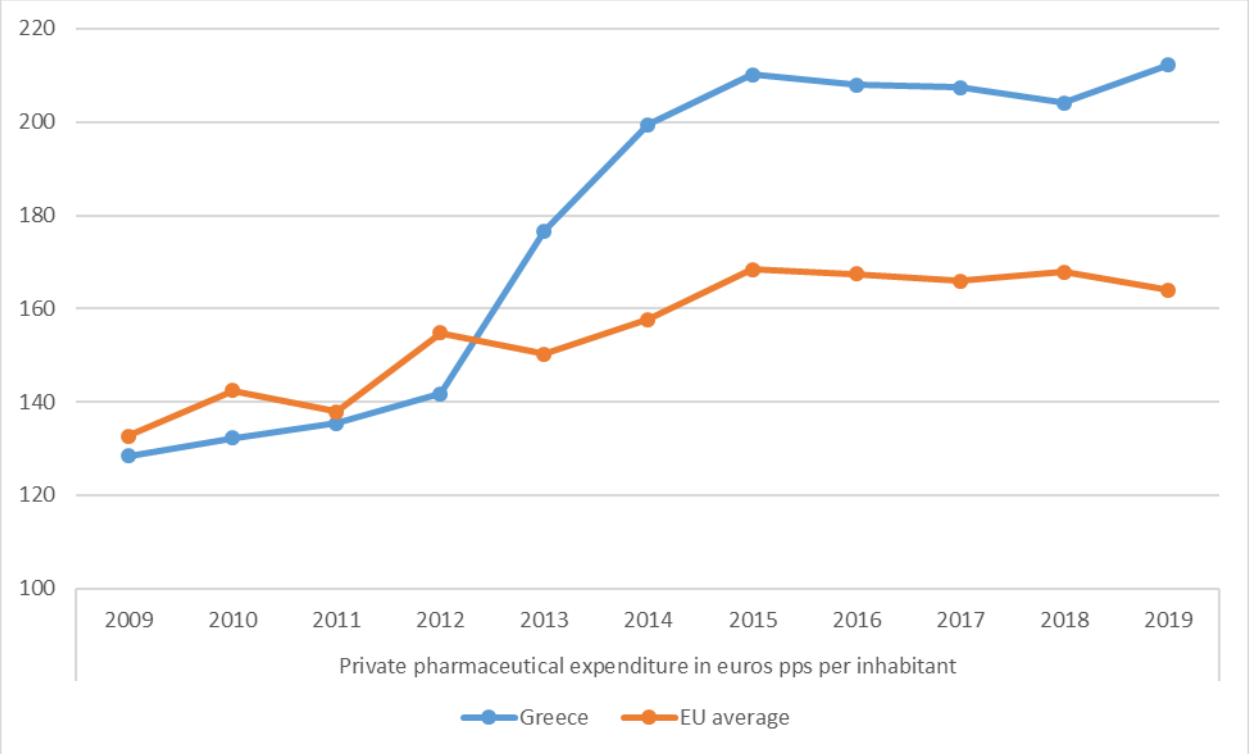
Source: Eurostat, accessed August 2022

7.3 Private pharmaceutical expenditure in euros pps per capita

Private pharmaceutical expenditure per capita in Greece presented a different trend in relation to the Greek public pharmaceutical expenditure. The substantial reduction of pharmaceutical expenditure in the public sector fostered a substitution effect - towards private expenditure. Private pharmaceutical expenditure per capita. Pharma expenditure in Greece, increased at a higher rate than the corresponding EU average.

Figure 20 presents the different paths of evolution of the private pharmaceutical expenditure in Greece and the EU average. In 2009 the private pharmaceutical expenditure per capita in Greece was €128.43 while in 2019 it increased by 65% reaching €212.24. The corresponding figures in EU average were €132.7 in 2009 and €164.0 in 2019 marking an increase by 24%. During the period 2009-2012 the gap between Greece and the EU average was rather small. However, the austerity measures implemented especially after 2012 led to the creation of an extra burden for the Greek households in the form of increased private pharmaceutical expenditure. The increasing gap between Greece and EU average regarding the private pharmaceutical expenditures is portrayed in Figure 20.

Figure 20. Private pharmaceutical expenditure in euros pps per capita



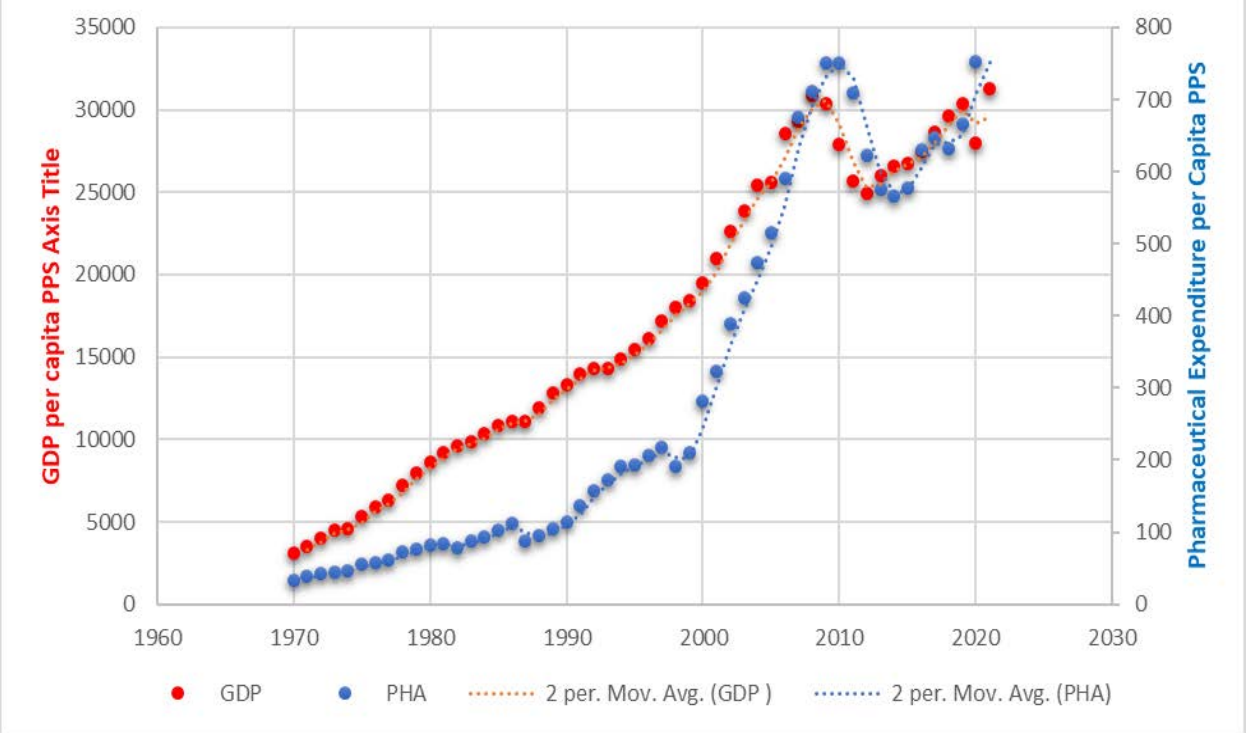
Source: Eurostat, accessed August 2022

7.4 Relation of Pharmaceutical expenditure with GDP

During the last decades the cost of pharmaceutical care has been increasing at a much faster rate than GDP. (Income elasticity >1). The rate of growth of pharmaceutical expenditures is attributed to several factors related to epidemiological profile, ageing of population, increase utilization, technological advancement, lifestyle changes, emergence of new disease, and increase in chronic diseases. Several countries across the world, both developed and rich industrialized nations, have adopted a variety of strategies to control the growing trends of health and pharmaceutical expenditures. The majority of implemented pharmaceutical policies focused on controlling prices, utilization, promoting generics, adopting new therapeutic choices based on cost effectiveness decisions and other overall demand and supply measures.

Greece is not an exception to this rule. In Figure 21 presents the evolution of per capita pharmaceutical expenditure in relation to per capita income.

Figure 21. GDP & pharmaceutical expenditure per capita pps 1970 -2021



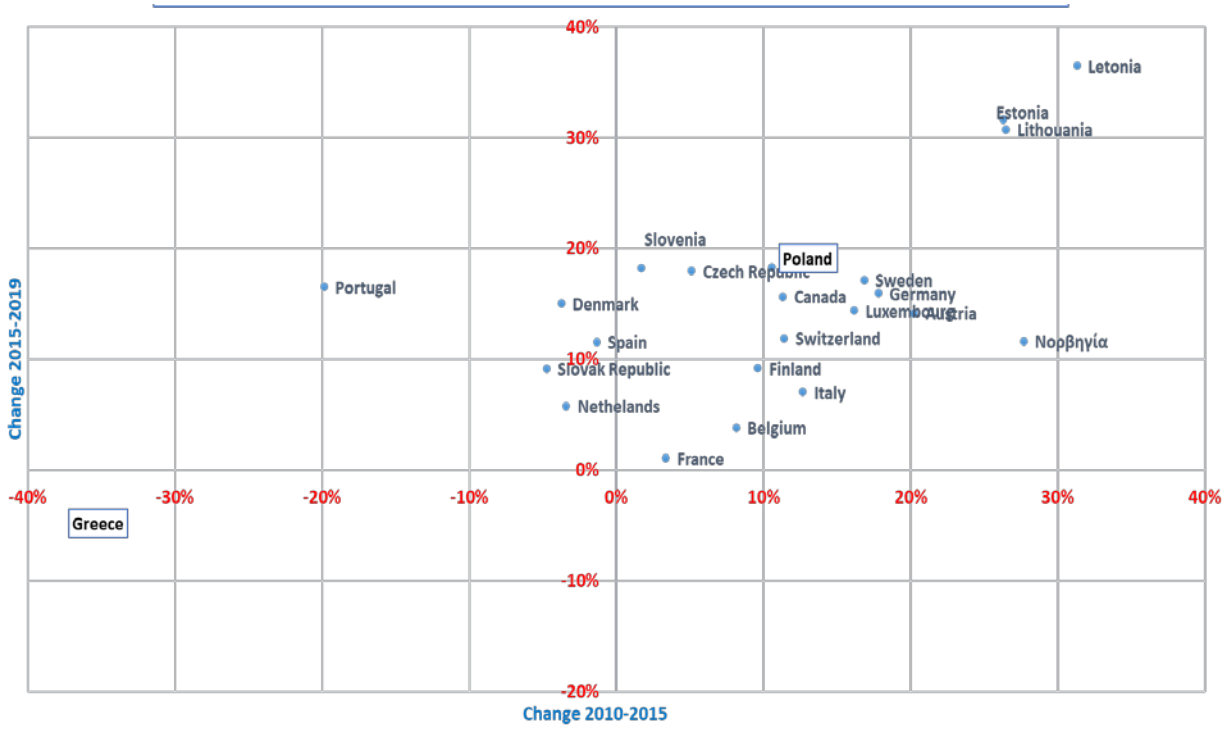
Source: OECD HEALTHDATABASE

Analyzing the Greek trends over the period 1970-2021 one may distinguish three periods. The first period (1970-1998) is characterized with an equal proportional increase between GDP and Pharma expenditure (elasticity = 1.02). The second period (1999-2009) refers to the lack of cost containment policies leading to overconsumption of medicines. Pharma expenditure increased twice as much as GDP (elasticity = 2.25). The third period (2010-2018) refers to the strict

memorandum measures imposing excessive cost containment measures leading to a negative relationship between pharma expenditure and GDP. The effects of memorandum policies on the pharma industry and the Greek health care systems will be discussed further in the relevant chapter dealing with the pharmaceutical policies in Greece

During the economic crisis 2009-2019, the economic climate changed dramatically in Greece. From a big pharmaceutical spender country, Greece became one of the lowest spenders among the European Union. Figure 22 depicts the extreme phenomena of increasing and declining trends in Greece. On the vertical axis the annual rate of growth in per capita pharmaceutical expenditure over the period 2015-2019 is portrayed while the horizontal axis refers to the same rate of growth over the period 2010 -2015. Greece appears to be the only outlier among the EU countries depicted in the scatter Figure 22 with the greatest changes in per capita pharmaceutical expenditure.

Figure 22. Change in pharmaceutical expenditure per capita in 2010-2015 & 2015-2019

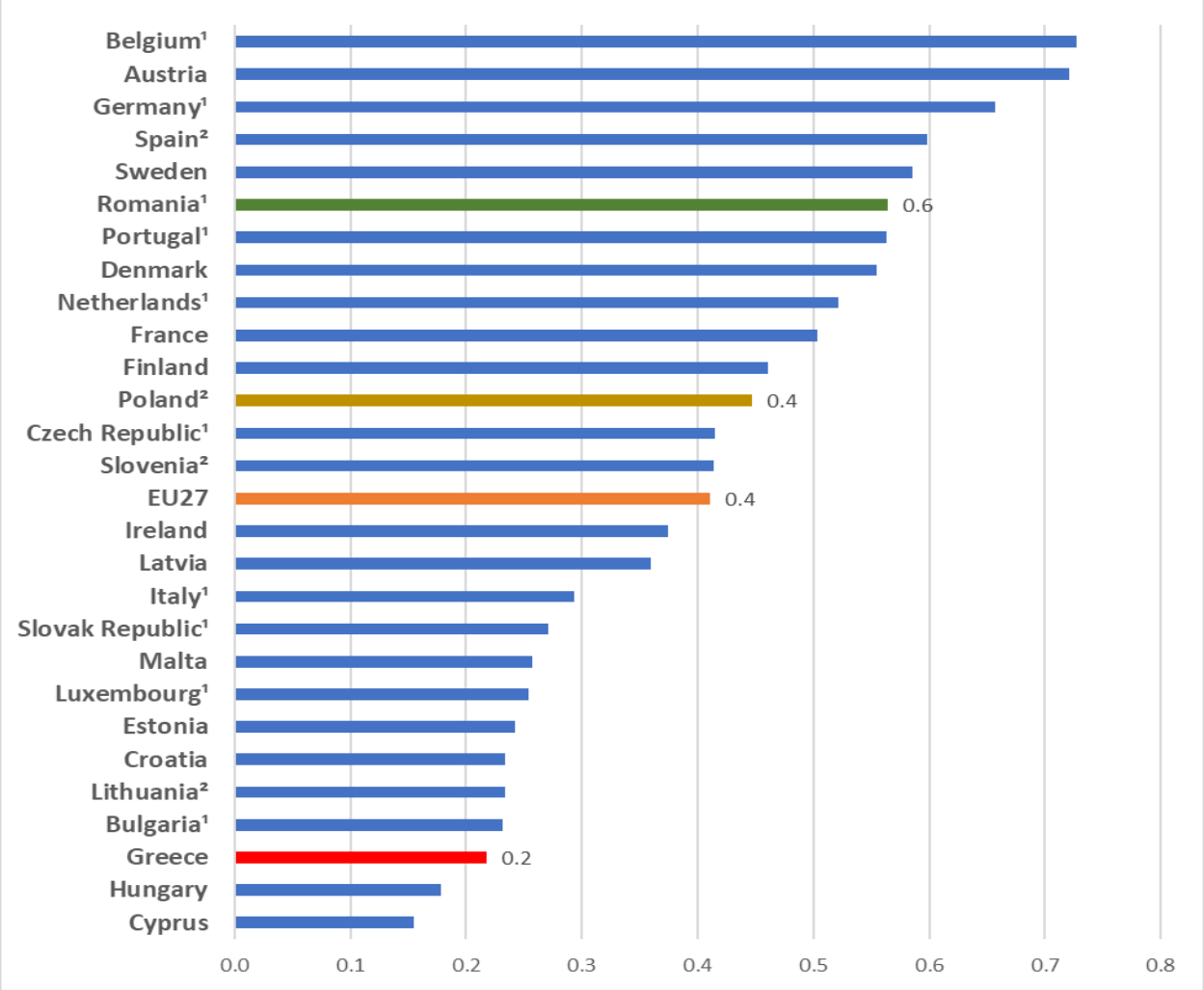


Source: OECD HEALTHDATABASE

7.5 Capital Underinvestment in the Health Sector

Capital investment on the health sector is approximated by the amount of expenditure on infrastructure, machinery, and medical equipment. This includes diagnostic and surgical machinery, ambulances, ICT equipment, software, and databases. Capital expenditure on health varies significantly among the EU Member States. In 2018 the EU Member States allocated on average around 0.4 percent of their GDP on capital investment. The largest spenders on capital investment in 2018 were Belgium allocating around 0.7% of their GDP. (Figure 23). The lowest spenders include Cyprus Hungary, and Greece investing around 0.2% of their GDP on capital expenditures. Decisions on health investment are strongly influenced by the economic cycles.

Figure 23. Capital expenditure on health as % of GDP

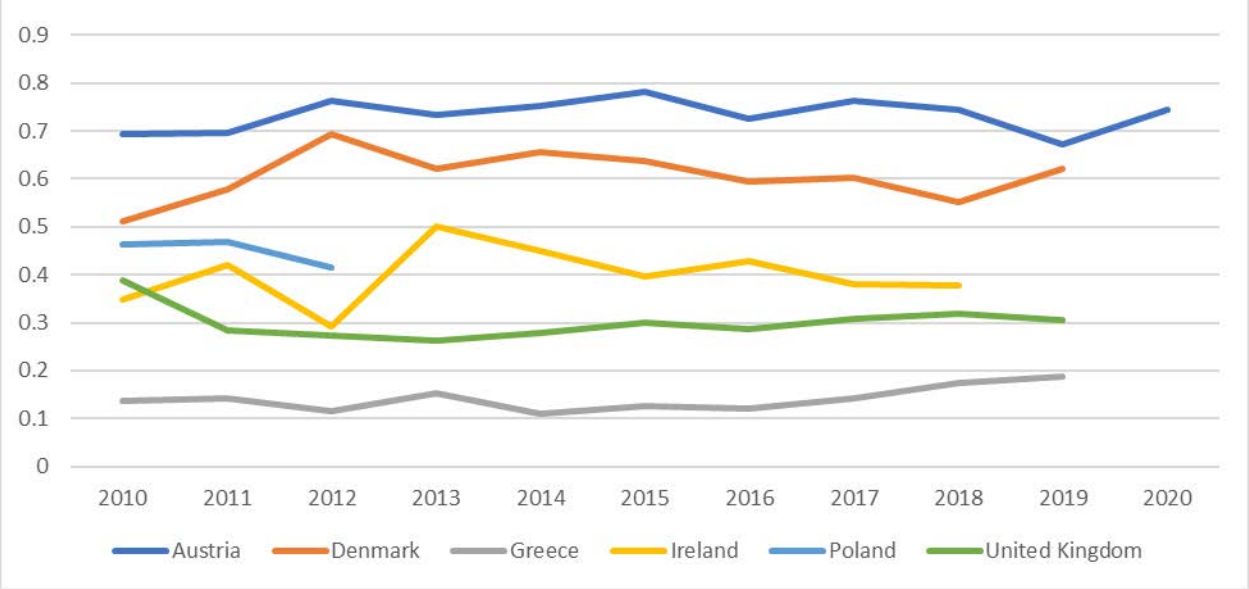


Source: OECD HEALTHDATABASE 2022

7.6 Time Trends

During the financial crisis and the years of increasing economic uncertainty capital spending is usually postponed. However, during the economic crisis some E.U Member States like Sweden and Austria maintained stable annual growths in health capital spending. Other Countries like Italy, United Kingdom and Greece witnessed a severe reduction in their health investment profiles

Figure 24. Health capital formation expenditure as % of GDP.



Source: OECD HEALTHDATABASE 2022

7.7 European Policies

In the European Union there have been several initiatives to promote capital investment in national health systems. Since 2014 the European Structural and Investment Funds (ESIF) provides various funds aiming at the reduction of regional and social health inequalities. In addition, the European Regional Development Fund (ERDF), the European Social Fund (ESF) and the European Commission have developed several investment programmes to increase the effectiveness, the efficiency, and the accessibility of health services across the EU Member States. During the COVID-19 the EU Funds increased substantially through the "Next Generation EU" recovery package.

7.8 Health Expenditure - main conclusions

Total pharmaceutical expenditure per capita in Greece between 2009 and 2019 decreased by 26%, (2009: €587.37;2019: €433.54). During the same period, the corresponding EU average trend increased by 3.6%, (2009: €388.62;2019: €402.69), so that the gap between EU and Greece was reduced significantly.

Public spending per capita for pharmaceuticals and other medical goods in Greece, decreased significantly, by -52% (2009: €458.94; 2019: €221.3) The corresponding EU average trend also decreased by 6.8%, (2009: €255.93; 2019: €238.67). Public pharmaceutical expenditure in Greece was significantly decreased between 2009-2014 as mandated by the Economic Adjustment Programs. After 2014 and up to 2019, Greece showed a significant reduction of the public pharmaceutical expenditure, closing the gap between Greece and the EU average. However, this goal was achieved through a series of horizontal measures that were proved unsustainable at the medium turn.

On the contrary, private pharmaceutical expenditure per capita in Greece followed a different path whereby the private expenditure was increased by 65% due to the reduction of the public one. pharmaceutical expenditure in the public sector fostered a substitution effect - towards private expenditure. The corresponding increase regarding the EU average was 24%. The austerity measures implemented especially after 2012 led to the creation of an extra burden for the Greek households in the form of increased private pharmaceutical expenditure.

From 1970 to 2010, Greece followed the common pattern among most of the countries of the world whereby pharmaceutical expenditure increased at a faster pace than the GDP. The acceleration of this trend especially for the period 1999-2009 is attributed to the lack of cost containment policies leading to overconsumption and therefore to a radical increase of the pharmaceutical expenditure. However, the cost containment measures imposed within the frame of the fiscal adjustments and austerity programs led to a significant decrease of the pharmaceutical expenditure which rendered Greece as one of the lowest spenders among the European Union.

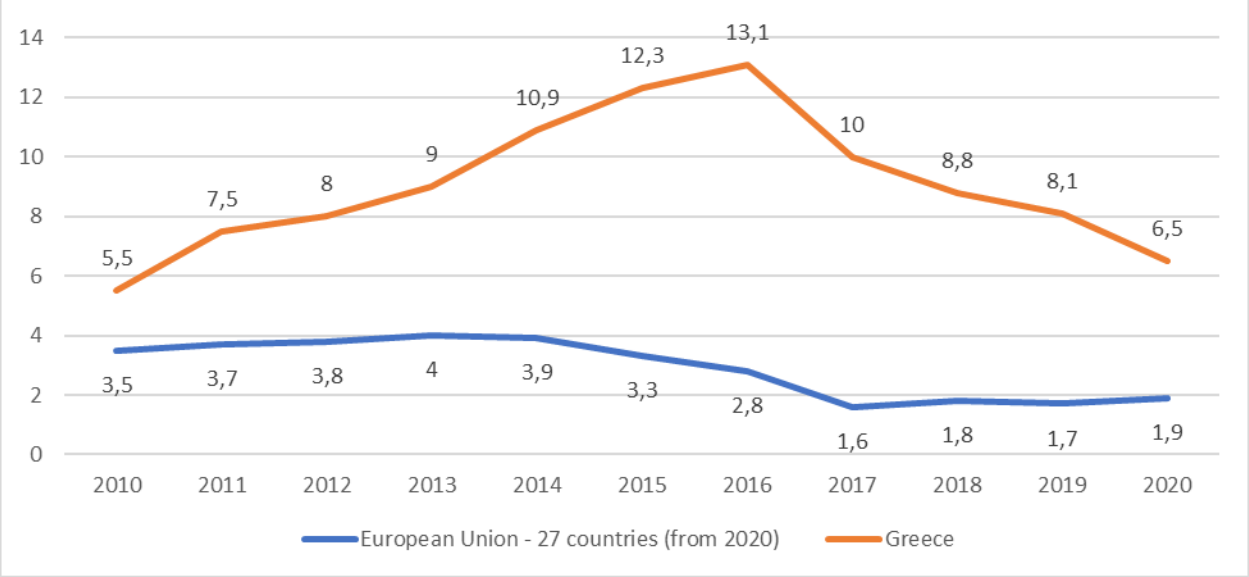
As a direct implication of the austerity period, Greece poses as one of the lowest investors in capital expenditures along with Cyprus and Hungary, investing a mere 0.2% of the GDP on health-related capital formation.

8. Health related unmet needs in Greece

The Eurostat collects data on unmet needs for medical care across the EU-27 Member States. Medical care refers to individual healthcare services (medical examination or treatment excluding dental care) provided by or under direct supervision of medical doctors or equivalent professions according to national healthcare systems. Data are collected from the European Statistics of Income and Living Condition survey and refer to such needs during the previous 12 months. Data are expressed as percentages within the population aged 16 years old and over living in private households. According to Eurostat[6] guidelines self-reported data are collected from the European Statistics of Income and Living Condition (EU-SILC) survey and refer to such needs during the previous 12 months. Data are expressed as percentages within the population aged 16 years old and over living in private households

Figure 25 presents the evolution of unmet needs for medical care in Greece in comparison to EU-27 average. On the base of the Figure 25 we may distinguish two period related to the impact and the duration of economic crisis in Greece. The first period 2010-2016 Greece presents considerable divergence in relation to EU-27 average Unmet needs increased in Greece from 5.5% in 2010 to 13.1% in 2016.

Figure 25. Unmet need for medical care – total population 2010 - 2020

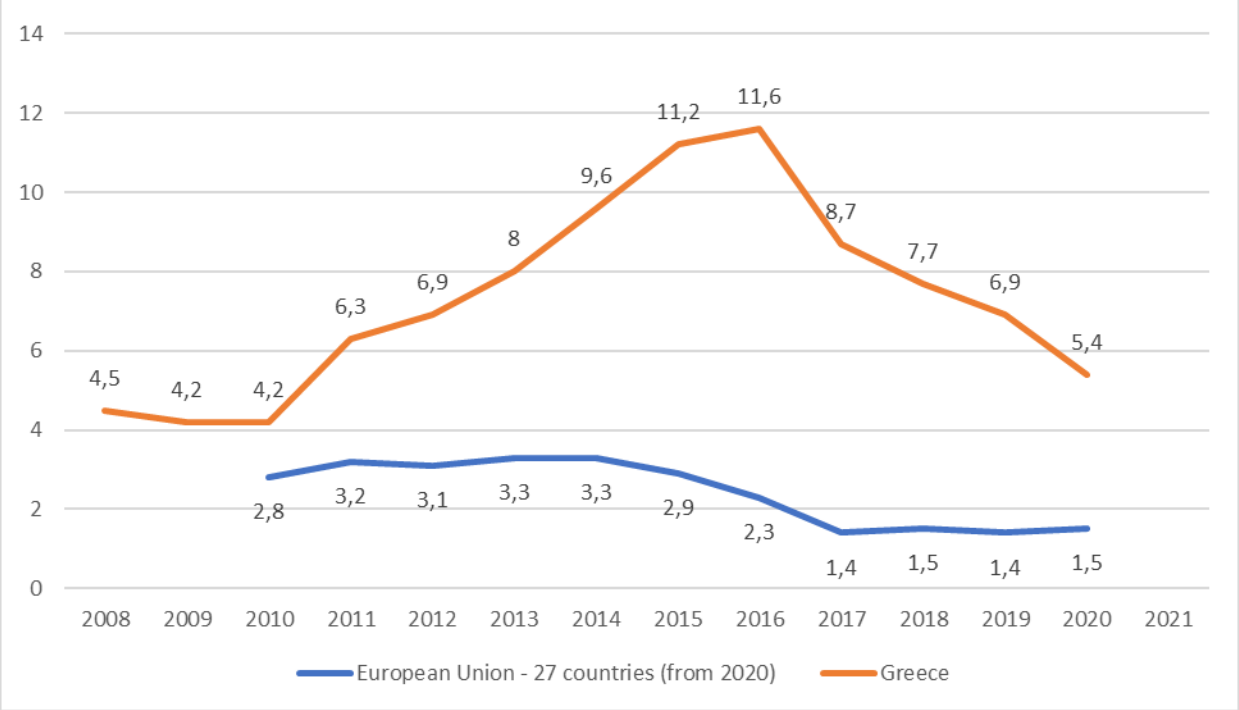


Source: Eurostat, accessed August 2022

Eurostat data https://ec.europa.eu/eurostat/databrowser/view/tespm110/default/table?lang=en (accessed 7.09.2022)[6]

This period coincides with the three Memorandum agreements between Greece and Troika. In the period 2017 to 2020 the gap in unmet needs was reduced but remained almost five time higher than the EU-27 average in the year 2020 (Greek 6.5 %, versus EU-27 1.9%).

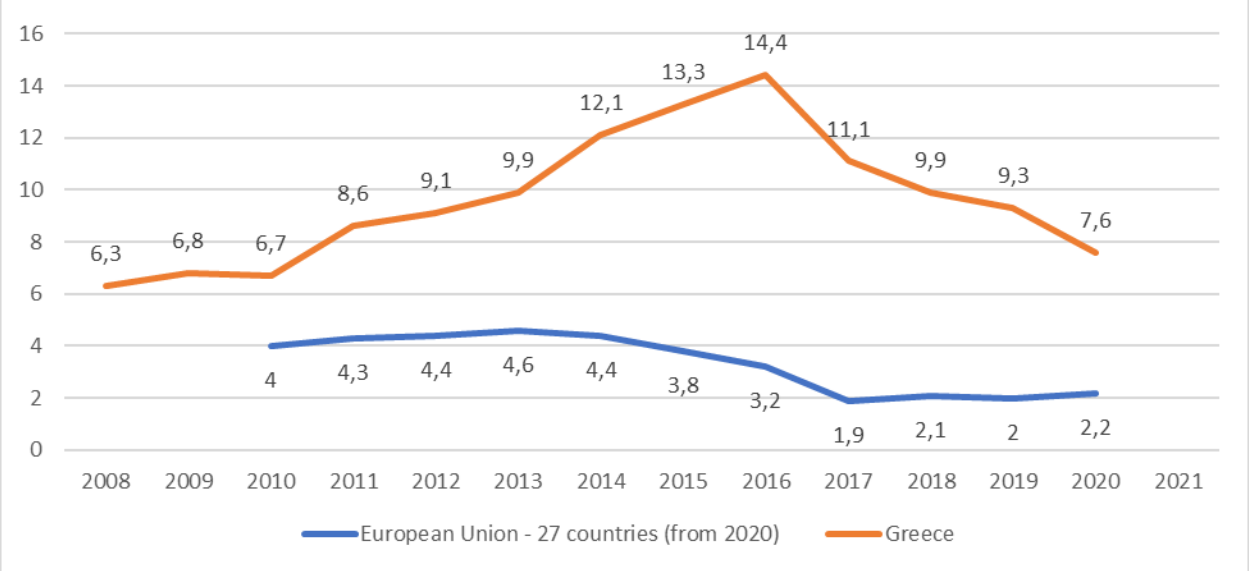
Figure 26. Unmet needs for male population 2008-2020



Source: Eurostat, accessed August 2022

Figure 27 presents the evolution of unmet needs for medical care for women in Greece in comparison to the correspondent EU-27 average. Unmet needs for women for medical care are significantly higher in Greece than in the EU during the whole examined period. As shown, the European Union remained stable at approximately 4% during 2010-2015, reporting a slight decrease to 1.9% in 2017. From 2018 to 2020, EU decreased from 4% in 2010 to 2.2%. Two period related to the impact and the duration of economic crisis in Greece appear with higher unmet needs for medical care. From 2010 to 2016 Greece reports an increase of 7.7% (from 6.7% in 2010 to 14.4% in 2016), reaching its highest point in 2016 when the gap averaged to 11.2%. After this period, improvement is observed followed by gradual narrowing of the existing gap. During 2017-2020, the gap between EU and Greece is approximately 7.8%. Overall, unmet needs for medical care in Greece increased 0.9% over the decade (2010-2020).

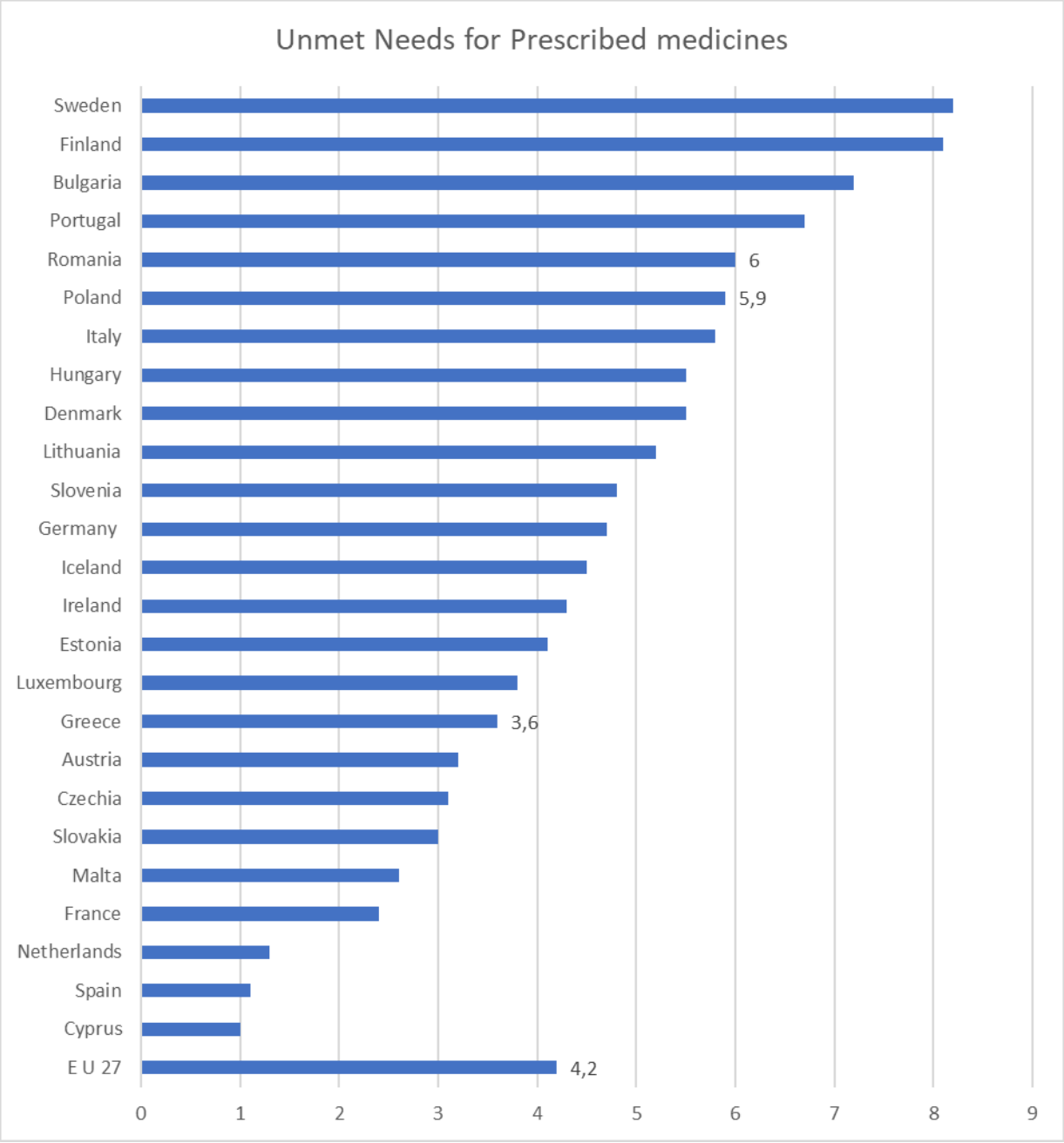
Figure 27. Unmet need for medical care, females 2008-2020



Source: Eurostat, accessed August 2022

As presented in Figure 28, Sweden dominates the first place in unmet needs for prescribed medicines while Finland and Bulgaria are not far away. Romania is 5th on the list with 6% and Poland is right above that with 5.9%. Greece remains lower with approximately 3.6%.

Figure 28. Unmet need for prescribed medicines 2020



Source: Eurostat, accessed August 2022

9. Pharmaceutical Policies in Greece

During the pre-crisis decade (2000-2009), Greece was the champion among the EU countries regarding excess over-prescribing and consumption of pharmaceuticals. It has been shown above that according to EU-23 statistics, total pharmaceutical expenditure in Greece had been at the highest levels in comparison to other EU countries with the same population. Notably, during the decade 2000-2009, total pharmaceutical expenditure increased steadily, with annual rates above the corresponding GDP growth rate, a trend which grew more intense especially after 2004. Structural problems, corrupted bureaucracy, lack of public governance, lack of e-prescribing for monitoring consumption, very high distribution margins and deficiencies in the drug chain from Government to pharmaceutical companies were among the contributing factors to this phenomenon.

In 2010 the Greek economy was set under international supervision and a series of reforms and fiscal targets were set regarding the health sector in order to reduce the cost and improve the economic efficiency of the health system. Pharmaceuticals were considered as a main field of intervention and within this framework, the restriction of public pharmaceutical expenditure was set as a priority in order to converge with the EU average as percentage to GDP. According to the MoU I&II signed between the Greek government and Troika, the outpatient pharmaceutical expenditure should be reduced to the level of 2.0 bn € by the year 2015 (2009: 5.1 bn €). This represented a reduction of 60.5%, which was mainly achieved through price cuts and the implementation of a rebate – clawback system.

The annual public pharmaceutical budget for the years 2016-2019 was set at 1.945 bn €, while in 2020 and 2021 a minor increase (up to 2.001 bn €) was decided. Furthermore, starting from 2016, a closed budget – clawback system was introduced for the hospital setting.

In order to attain this objective, the Greek government has launched a series of cost containment measures. Table 1 presents briefly the policy interventions for the control of pharmaceutical expenditure.

Table 1. Government's measures to control pharmaceutical expenditure

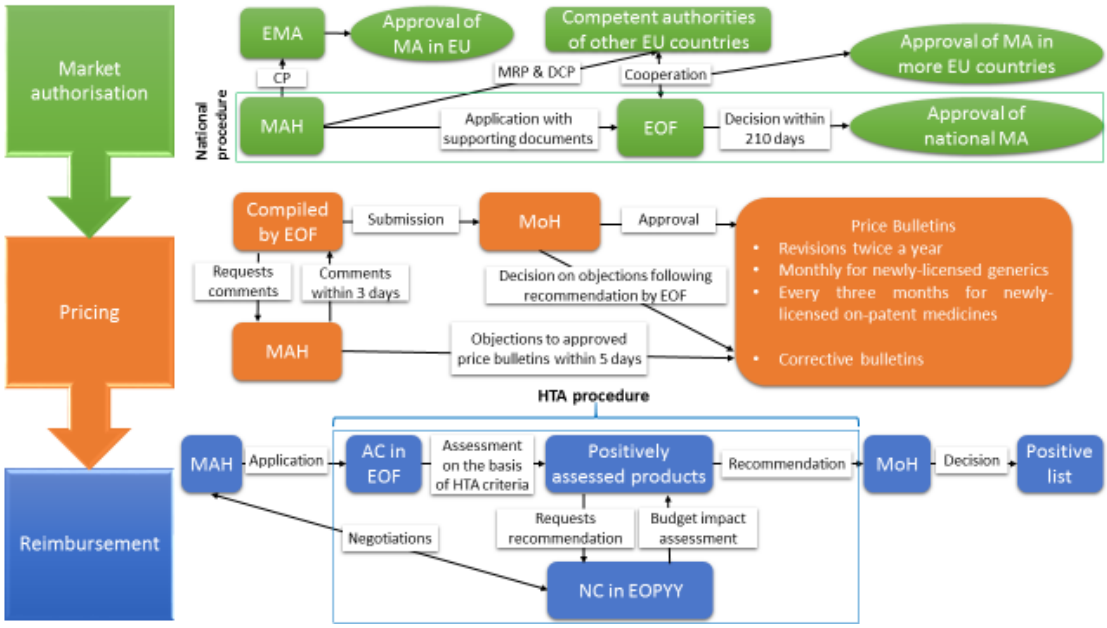
1. Introduction of a positive list for medicines reimbursed by EOPYY (the main SSF representing ~95% of the insured population)
2. Introduction of a negative list for medicines not reimbursed by EOPYY, of an OTC list and of a list of High-Cost medicines related to severe diseases
3. Obligatory INN prescription and specific targets regarding penetration of generics
4. Restructure of wholesalers' and pharmacists' margins
5. New pricing system and bi-annual general price revisions
6. Implementation of a DRGs system at the hospitals

7. Introduction of a rebate system mainly for MAHs
8. Closed budget and clawback for MAHs if annual budget is exceeded
9. Economic incentives to patients to promote the use of generics
10. Introduction of an e-prescription system
11. Establishment of therapeutic/ pharmaceutical prescribing guidelines
12. Restructure of co-payment levels for specific diseases (i.e COPD, Alzheimer etc)
13. Provision of High-Cost medicines through EOPYY's own pharmacies and hospitals
14. Contracts with health providers

9.1 Marketing authorization

The market authorization, pricing and reimbursement processes in the Greek pharmaceutical sector are outlined in Diagram 2.

Diagram 2. Market authorization, pricing and reimbursement processes in the Greek pharmaceutical sector



Note: AC, Assessment Committee; EMA, European Medicines Agency; EOF, National Organisation for Medicines; EOPYY, National Organisation for the Provision of Health Services; HTA, Health Technology Assessment; MA, market authorisation; MAH, Market Authorisation Holder; MoH, Ministry of Health; NC, Negotiation Committee.

There are three procedures whereby a medicinal product is granted market authorisation in Greece:

- the centralised procedure of the European Medicines Agency (EMA),
- the mutual recognition and decentralised procedures with other EU member states, and
- the national procedure.

The National Organization for Medicines (EOF) is the regulating authority regarding marketing authorization for medicines, following an application (from companies established only in the EU) accompanied by supporting documents. IFET, a public entity supervised by EOF, may

import any product in special cases of life threatening diseases [31] or in cases of public health concerns [32].

9.2 Distribution and dispensing

Medicinal products are distributed by the pharmaceutical companies in the Greek pharmaceutical market either through wholesalers to pharmacies or directly to public hospitals, while the industry can also sell pharmaceuticals directly to pharmacies. In special cases (e.g. mobility issues of patient), companies can deliver products directly to patients following permission from EOPYY [20].

Medicinal products are dispensed exclusively by the 10,674 private pharmacies, hospital pharmacies, and the 29 pharmacies belonging to the EOPYY [26, 29]. High-cost pharmaceuticals for severe diseases that are only for hospital use or with a retail price above €3,000 (Law 3816/2010) are dispensed exclusively through hospital or EOPYY's pharmacies [7, 29].

9.3 Pricing

Pricing has been a field of extensive reforms since 2009, as a convenient tool to control expenditure. The responsibility for the pricing of pharmaceuticals has been transferred from the General Secretariat of Commerce of the Ministry of Development to the Ministry of Health and EOF in an effort to improve the efficiency of the decision-making process and administration [3]. Price lists regarding repricings and prices of new medicines are issued with a ministerial decision in a Price Bulletin [33].

Two major across-the-board cuts of the wholesale price of medicines with an estimated weighted average of 21.5% and 10.2% were applied in 2010 and 2011, respectively [35, 36], followed by repeated repricings especially focusing on generics, as a direct measure to incentivize their use. However, price decreases for generics were implemented as a stand-alone intervention, not intergraded with supplementary measures to control the unjustified switching to more expensive medicines i.e., biding prescribing protocols, economic incentives for generics at the pharmacy level, awareness campaigns for the use of generics etc. Therefore, it is of no surprise that despite a decade of steep price cuts, generic use in terms of volume, remains at the lowest level among the EU countries. Moreover, extreme price pressure combined with the ever-increasing clawbacks, and the lack of coherent policies towards the use of the more economic alternatives, created a toxic business environment, which have resulted e.g., in 2019 at the withdrawal of ~42.6% of the generics present at the 2014 positive reimbursement list, due to lack of sustainability. Furthermore, the repeated price reductions, incentivized parallel exports which in many cases distorted the local market equity, creating shortages [3].The basic features regarding the present state of pricing in Greece are following

Pricing and repricing timeframe

New products (non-generics) are priced on a quarterly basis. New generics are set to be priced on a monthly basis, however in practice they are priced, on average, every three months.

General repricing applies regularly on a yearly basis - in December. However, according to recent legislation (L.4865/Dec.2021), starting from 2022 the general repricing could apply exceptionally earlier in the year as a means to control expenditure (not implemented so far)

Pricing rules

On patent (legal base 8.3) and off patent (8.3 after LoE 7, 10.3, 10.4, 10.a, 10.b, 10.c) are priced at the average of the two lowest prices of the same product (identical strength and package) among the Eurozone countries (External Reference Price- ERP). If no such identical products exist, products with different strengths and package sizes can also be taken into account.

Information regarding the prices in the Eurozone countries are retrieved from the EURIPID database and the relevant official country data. In case that the strength and/or package are not identical, further reduction rates apply up to -12%. Generics (legal base 10.1) are priced at 65% of the price of the reference product.

Repricing limits/waivers

Price increases are not allowed (overriding the ERP rule). Price decreases cannot exceed 7% in each repricing. However, recent legislation (L.4865/Dec.2021) provides that this percentage limit can be especially altered by the MoH at the earlier general repricing (effective from 2022, not implemented so far).

A reprising waiver is applied for all products with Daily Treatment Cost (DTC) < = 0.2 EUR (calculated in retail price). Moreover, the 0.2 EUR limit serves as a price floor i.e., the price of a product can only be decreased down to the point where its DTC reaches the limit of 0.2 EUR.

Unlimited voluntary price decreases are allowed, twice a year per product: one after the general repricing and another one anytime in the year. Especially, reference off patent products cannot decrease their price lower than the price of the corresponding generics and generics are not obliged to follow the rule of 65% of the new price of the reference product after the voluntary price decrease.

Price structure

The base of the repricing is the ex-factory price (EX-F) i.e., the price in which the industry sells to wholesalers (voluntary discounts not included). Ex-f is the starting point from which all price levels derive

[7] LoE: Loss of Exclusivity

Table 2: Price structure

	Rx - reimbursed	Rx – non reimbursed
Wholesaler price (WP)	EX-F <= 200 EUR: 4.9% over the EX-F	5.4% over the EX-F
	EX-F > 200 EUR: 1.5% over the EX-F	
Retail price (RP)	*WP + markup (see table 2) + VAT (6%)*	35% over the WP + VAT (6%)
Hospital price (HP)	EX-F minus 8,74%	

Table 3: Rx -reimbursed-retail price

WP	markup	WP	markup	WP	markup
0-50.00	30%	500.01-600	8.00%	1,500.01 -1,750	3.75%
50.01-100	20%	600.01-700	7.00%	1,750.01 – 2,000	3.25%
100.01 -150	16%	700.01-800	6.50%	2,000.01 – 2,250	3.00%
150.01-200	14%	800.01-900	6.00%	2,250.01-2,500	2.75%
200.01-300	12%	900.01 -1,000	5.50%	2,500.01 – 2,750	2.50%
300.01- 400	10%	1,000.01 -1,250	5.00%	2,750.01 – 3,000	2.25%
400.01-500	9%	1,250.01-1,500	4.25%	>3.000.	2.00%

Additional discounts

MAHs can provide unlimited voluntary discounts over the Hospital Price for products supplied to hospitals, private clinics and EOPYY's owned pharmacies.8 MAHs can also provide additional voluntary discounts to reach a total of 10% over the EX-F price, for Rx products supplied to wholesalers

Wholesalers can provide unlimited voluntary discounts for the High-Cost Medicines and additional voluntary discounts to reach a total of 10% over the wholesaler price for Rx products supplied to the pharmacies

[8] EOPYY is the main Social Security Fund representing ~98% of the insured population. EOPYY owns 35 pharmacies providing high-cost medicines to patients with zero copayment.

Issues of concern

The actual price level of medicines in Greece

Over the recent years, international comparisons regarding the average price level of medicines have drawn much attention by ranking the price level of generics in Greece as the highest among the EU countries. Therefore, further price decreases for generics in Greece would seem as a reasonable and justified policy choice. However, these comparisons are generally misleading due to the following:

- The impact of rebate and clawback is not considered. Mandatory rebates and clawback in Greece are the highest across the EU, accounting in 2021 to ~42% on average over the ex-factory price of generics. In contrast, to our knowledge, generics are exempted from rebate and/or clawback in many EU countries[9].
- Values (prices) should not be interpreted irrespective of volumes. Despite the steep price cuts especially for generics, Greece still marks the lowest generic volume penetration in the EU[10].

[9] See "*Assessing the net price level of generics In Greece: The effect of compulsory paybacks"*, poster presentation at ISPOR 21st 2018 Annual European Congress.

[10] According to EOPYY data, generics account for ~24.5% in volume at the reimbursed outpatient market, while the correspondent target set by the fiscal adjustment programmes over the past decade was initially 60% and later 40%. It is worth noted that IQVIA reports generics market share as ~35%, including off-patent medicines with legal basis other than generics i.e. hybrids, fixed combinations, etc.

9.4 Reimbursement

In mid-January 2018, a major overhaul of the reimbursement system was introduced [34]. The PRLC has been replaced by the Assessment and Reimbursement of Medicines for Human Use Committee (Assessment Committee or AC), which practically served as a precursor HTA body. The AC is staffed by 11 experts in fields related to health technology assessment, supported by a scientifically specialized Secretariat. The experts and the Secretariat are appointed by a decision of the MoH. The basic features regarding the present state of reimbursement in Greece are following

General

Both negative (non -reimbursed) and positive (reimbursed) lists in place. The positive list, groups the medicines nominally at the ATC4 level. However, there are many exemptions, so the positive list follows a rather hybrid scheme between ATC4 and ATC5 levels. Reimbursed products may be classified into distinct groups (ATC-5 clusters), or sub-clusters in case they are considered as non-interchangeable or come with a different formulation, etc. Notably, 610 out of 1,085 clusters of the positive list (July 2021), contain only 1 brand and therefore are reimbursed at retail price.

Assessment criteria

The AC is responsible for the inclusion/exclusion of newly-licensed medicines in and the revision of the positive list [34]. The basic assessment criteria are already defined by the enacting law: a) clinical benefit, b) comparison with other reimbursed medicines, c) reliability of data, d) cost-effectiveness, and e) budget impact. The final recommendation may also include specific therapeutic indications, limitations and specifics over the place of the product at the prescribing protocols. These protocols are expected to be associated with the development of the corresponding patient registries, as Greece still lacks of such systems. The new e-prescription system can provide the basis for the establishment of patient registries, as it collects unique real-world information. In this regard, patient registries for hepatitis C and chronic myelogenous leukemia have started collecting data since September 2015 and March 2016, respectively [7]. Another patient registry for lung cancer has also been launched recently and started collecting and digitizing retrospective data.

Assessment procedure

The process of assessing a newly-licensed medicine commences with the application of the MAH, accompanied by a full dossier, and the payment of an entry fee [34]. Requesting recommendations from external experts is now also possible. For products with an initial positive assessment, a recommendation is requested from the Negotiation Committee (NC) concerning their budget impact. The NC is also established by the new legislation, assuming the competences concerning pharmaceuticals of the existing respective committee in EOPYY, and its members are also appointed by the Minister of Health. The NC is responsible for initiating

and completing the negotiation with MAHs regarding the prices and discounts of medicines reimbursed by EOPPY or procured by public hospitals. Upon the receipt of the budget impact assessment, the AC forwards its final recommendation to the MoH for final decision and issuance of the positive list with a ministerial decision.

Furthermore, it is mandatory that the AC assesses: a) all on-patent products that have been included in the positive list during the previous three years in a triennial procedure, and b) all included in the positive lists products that are therapeutically equivalent to medicines for which an inclusion application has been submitted [34].

Currently, medicinal products in the positive list are categorized between a) high-cost medicines administered in hospitals for the treatment of serious diseases of Law 3816/2010 and b) all other medicines [7]. Furthermore, the positive list is compiled on the basis of the fourth level of the Anatomical Therapeutic Chemical Classification system (ATC4), which also serves as the basis for the internal price referencing system [7]. A reference price is calculated for each available strength and/or pack size of pharmaceuticals in each cluster.

Reimbursement price calculation

Reimbursement prices are set through an Internal Reference Price system (IPR). The Reimbursement Price is calculated by the Reimbursed Daily Treatment Cost (DTC) multiplied by the dosages per pack. There are 2 methods to calculate the reimbursed DTC and the one which yields the lowest value is considered i.e.:

- The lowest between (a) the weighted average (by values) DTC of all reference products (both on & off patent) in the cluster and (b) the weighted average (by values) DTC of the generics in the cluster.
- The weighted average (by values) of the lowest DTC of the generics which cumulatively hold 20% (by volume) during the semester prior to the price calculation, among the generics of all the molecules included at the cluster with the same strength e.g., 20mg and form e.g., tabs.

9.5 Co-payments

Since 2006, a three-tier co-insurance system is in force: a) 0% for life-threatening diseases, b) 10% for specific chronic diseases, and c) 25% for all the other types of diseases [38, 40]. In cases where the retail price of the chosen medicine is higher than the reimbursed price [7, 29]: a) if the product has generic counterparts in the market, the extra billing is covered entirely by the patient on top of the cost-sharing requirement, and b) if there are no generics for the product, the patient covers only half of the difference, and the other half falls upon the MAH in the form of a rebate. Since 2016, a ceiling of €20 per pack has been placed on the maximum amount a patient could pay on top of the cost-sharing rate. In cases where the retail price is lower than the reference price, then up to 50% of the difference is deducted from the co-insurance contribution. Also, a fixed fee of €1 per prescription is paid directly by patients since 2014 [8, 9].

Out-of-pocket pharmaceutical payments and provisions for vulnerable groups

A qualitative review of the Greek legislation demonstrated that about 59.8% of the recent reforms in the pharmaceutical sector has shifted cost to consumers [41]. The average pharmaceutical cost-sharing increased from 13.3% to 18% between 2012 and 2013 [9], and the mean patient charge per prescription was enlarged by 65.2% between 2011 and 2014 [8]. As a result, out-of-pocket payments (OOP) for medical products have risen significantly during the economic crisis. A study found that the mean household medicinal OOP increased by 25.8% (from €249 to €313) between 2008 and 2014, which disproportionally burdened the budget of the poorest quintile [42]. The increased burden of the pharmaceutical OOP along with the diminishing ability-to-pay of households during the economic crisis may induce a significant welfare degradation to vulnerable groups in terms of both financial hardship and barriers to necessary pharmaceutical care [43, 44].

Before the economic crisis, uninsured patients were burdened with the entire outpatient pharmaceutical cost themselves, unless they were eligible for a poverty booklet, which provided entitlements to free of charge medicinal as well as inpatient and primary care through the network of the ESY [6, 45]. The poverty booklet still remains in force, and its eligibility criteria are a) permanent and legal residency in Greece, b) lack of insurance, and c) low income (annual family income not exceeding 6.000 euros, which increases by 20% for the spouse and every under age or dependent child) [6, 45]. In mid-2014, coverage was expanded to all uninsured Greek citizens and legal residents not eligible for a poverty booklet, granting access to pharmaceuticals with the same co-payments that apply to the insured [6, 45]. However, the closed budget remained the same. These additional measures were of limited success due to bureaucratic barriers, stigmatising procedures and insufficient public information, not to mention the fact that high copayments still created significant economic difficulties in poor uninsured patients [45, 46]. In 2016, new provisions were instituted to overcome some of the weaknesses of the previous legislation. Coverage was expanded to specific vulnerable groups (e.g. pregnant

women, refugees and minors) and people without residency status [21, 45, 46]. In mid-2017, a new legislation was enacted that provided full exemption from or a deduction to their co-payments to extremely poor individuals not covered by other provisions [47, 48]. [49].

9.6 Mandatory rebate and clawback

Public pharmaceutical expenditure is reduced after the deduction of rebates paid mainly by pharmaceutical companies, which were increased during the recent years, and, to a far lesser degree, by private pharmacies (since 2011) [3, 7]. The basic features regarding rebate and clawback in Greece are following

Rebate mechanism

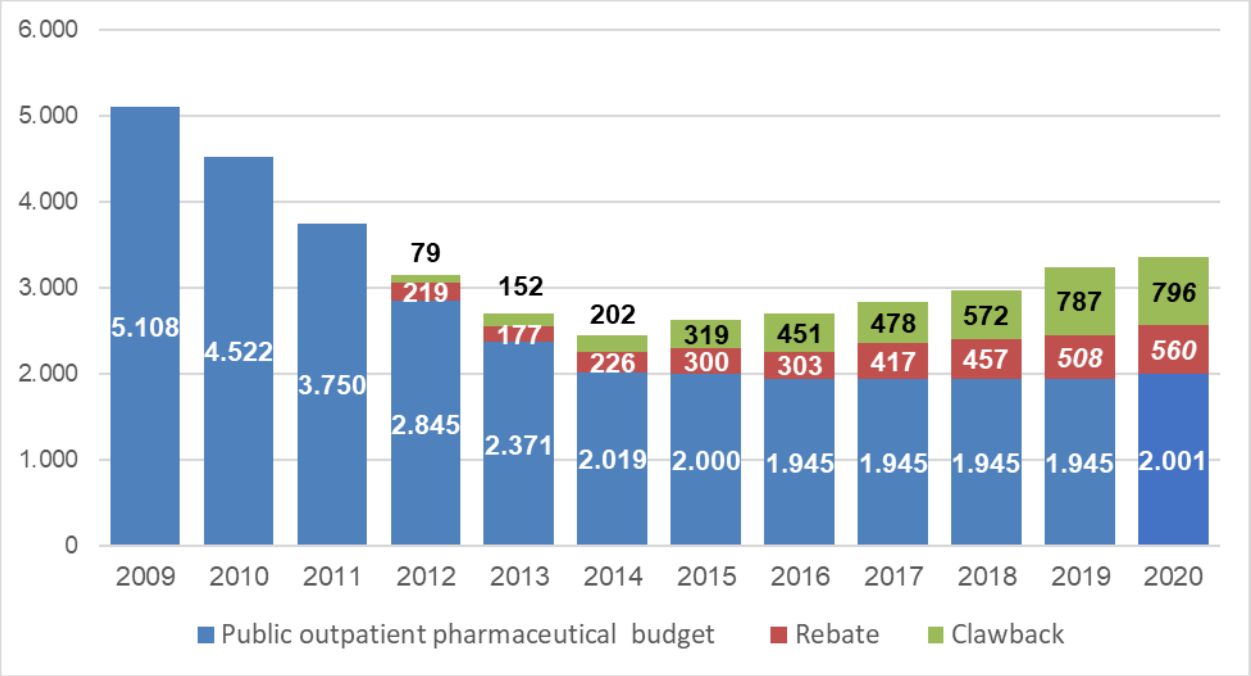
Compulsory rebates ranging from 14% to 30% over the ex-factory price apply to all reimbursed products (outpatient and hospital) on a trimestral basis. Rebates are calculated with a polynomial formula, which factors the brand's sales and characteristics. Recently, an additional rebate of 5% for the on-patent products of the positive list was introduced, to compensate the fact that they are reimbursed at retail price as being categorized uniquely in the cluster.

Clawback mechanism

The clawback mechanism was introduced in 2012 within the frame of the 2nd Economic Adjustment Programme, as a measure to safeguard the fiscal stability of the public pharmaceutical care system. A pharmaceutical budget limit was set and any amount in excess of this limit would be returned from the pharmaceutical companies to the State. Initially, up to 2016, the budget limit and the clawback system was implemented only at the outpatient pharmaceuticals reimbursed from EOPYY. In 2016 the mechanism was also extended at the in-patient /hospital setting. Moreover, in 2016 pharmaceutical coverage was extended to also include all uninsured population in Greece. However, the annual budget limit was not accordingly increased. The additional cost for 2016 was ~60 mn. € whereas the cost for 2021 was 310 mn. €. These amounts contribute to the increase of the clawback. The insufficient low level of the budget limit, the inclusion of the uninsured population lacking provisions for a budget increase, the introduction of new costly medicines, and the lack of demand side measures to control the cost and promote the rational use of medicines, led to the escalation of clawback from 78 mn. € in 2012 (budget limit 2,880 mn €), to ~796 mn € in 2020 (budget limit 2,001 mn €) at the outpatient setting. If the hospital clawback is also considered, the total clawback amounts to ~1,2 bn €, a significant amount that threatens market sustainability. Rebate and clawback in total summed up to ~1,8 bn € in 2020.

As it is shown in Figure 29, the contribution of pharmaceutical companies in the form of rebates and clawbacks to the actual public outpatient pharmaceutical expenditure has increased significantly from 9.4% in 2012 to 40.3% in 2020 [29].

Figure 29. Public outpatient pharmaceutical budget, rebate & clawback 2009-2020



Source: EOPYY official rebate & clawback notices to MAHs

Clawback calculation:

At the end of each semester, the clawback is calculated as the difference between the budget limit and the final expenditure, i.e., the gross spending minus

- patient copayments,
- mandatory rebate ranging from 14% as an entry level up to 30% according to sales volume,
- voluntary discounts provided by the companies

Clawback allocation:

Initially the clawback was allocated to all the companies according to their market share. This has had a detrimental effect especially for generics and the older/ cheaper products: although the budget excess was fuelled by the new expensive on patent medicines, it was allocated to all products, even to generics.

In 2017, the allocation method was changed whereby 90% of the clawback was attributed to the company's market share (share parameter) and 10% to the company's share in growth, i.e., the (positive) difference between a) the total sales of the current semester and b) the total sales of the same semester at the previous year (minus the corresponding clawback). Vaccines were permanently exempted from the growth parameter. Generics were exempted from the growth

parameter for the first 2 years after the market launch. This created a new distortion since generics were burdened enormously the third year after launch with the cumulative growth of the previous 2 years.

Starting from September 2020, the cost for vaccines is exempted from the public pharmaceutical expenditure, so the relevant cost is not included in the outpatient budget limit.

Starting from the second semester of 2020, the 90/10 allocation rule has changed to 80/20 with the permanent exemption of generics and off-patents from the Growth parameter (20%). However, the new rule was applied only at the outpatient setting – (hospitals still follow the 90/10 rule). This again was changed recently (2022): Clawback allocation returned on market share basis (the Growth parameter was abolished) and the outpatient budget is reallocated between a) the High-Cost medicines dispensed by EOPYYs own pharmacies and the medicines dispensed by the community pharmacies. This is expected to improve the clawback allocation for generics.

The RRF programme for the healthcare sector introduced two reforms regarding the clawback which are at the right direction although do not provide a sustainable environment

- A limited contribution of the State (by the form of an increase of the budget limit) in case that the annual goals to decrease the clawback are not met (in effect from 2022 up to 2025).
- An incentive for investments allowing the offset of a relatively small part of the clawback with R&D expenses (total 250 mn € for a three-year period).

Prescribing and promotion of generics

Overprescribing or prescribing specific brands or medicines has long been an issue in the Greek pharmaceutical market [2, 35]. Hence, several measures were recently adopted to rationalize prescribing patterns and levels. Mandatory e-prescription and prescription by International Non-proprietary Name (INN) for all therapeutic categories of the positive list (at first on a pilot basis for 10 active substances with the highest consumption) have been introduced since 2012 [40]. Prescription by brand name is allowed only in specific cases (e.g., patients with allergic reactions, transplant and immunocompromised patients, blood derivatives, insulins, vaccines, biotechnology and combination products, drugs with narrow therapeutic range, medicines for epilepsy, psychosis, schizophrenia, asthma and chronic, degenerative and autoimmune diseases), which are posted on EOF's website [9, 40]. These exemptions as well as all other deviations from the compulsory prescribing by active substance should be duly reasoned and cannot exceed 15% of the total annual prescriptions issued by each physician. Prescribing patterns of physicians are closely monitored through the web-based application of the HDIKA used for e-prescription, which also supports the management and monitoring of referrals, diagnostics and other medical acts [2]. Detailed auditing on pharmaceutical prescription and expenditure is supposed to be carried out monthly, and penalties could be imposed on noncomplying physicians [21].

Along with the mandatory e-prescription, a compulsory use of therapeutic protocols for physicians based on international prescription guidelines was also established in 2012 [3, 21]. These protocols can allow for a greater control of prescribing behavior and guiding prescribing choices towards the cheapest medicines. Since then, prescription guidelines are gradually being developed and incorporated into the system. Until April 2018, only 7 basic therapeutic protocols have been posted on the webpage of MoH, but the number is expected to grow in the upcoming months. However, protocols can be by-passed rather easily since the relevant results of the examination which unlock the protocol steps are still filled manually by the physicians.

Following early 2014, the government has started to place more focus on reducing medicine consumption and to encourage rational prescribing in order to dampen pharmaceutical spending. A spending cap was set on the monthly amount prescribed by a physician (80% of the previous year's prescription budget) [6]. In the new framework, a number of patients were forced to refer to several doctors so as to find one that had not reached their prescription limit [9]. For this reason, exceptions to the prescription limits were introduced for physicians who work at public hospitals as well as those who work for retirement facilities and NGOs [3]. Furthermore, a new amendment set prescribing limits depending on physician's specialty, the number of patients for whom the physician prescribes, the geographical area and the month of the year [9]. Specific categories were exempted from these rules, such as end-stage chronic kidney disease, patients with hepatic insufficiency, cancer patients, end-stage cardiomyopathy, transplanted patients and vaccines [50]. Also, monthly minimum percentage prescribing thresholds of off-patent medicinal products per physician were established; since mid-2015 these thresholds refer to generics [51]. These targets are monitored via the e-prescribing system, and a reward-penalty system is applied. More recently, the regulatory framework has been updated, and an average target of 60% share of generics prescription in terms of volume for outpatients has been defined [49]. Furthermore, ten assessment indicators of the individual prescription behavior have been determined, such as number of prescriptions, mean number of prescriptions per insured, mean cost per prescription and prescribing share of new active substances; a similar process was also established for the assessment of the dispensing behavior of pharmacies.

Since 2017, the economic incentives for pharmacists to support generic substitution have been enhanced [49, 52]. The fulfillment of monthly share targets (25% of all prescriptions for 2017) are associated with compulsory deductions up to 10.5% from pharmaceutical companies.

Despite the adoption of several measures of generics substitution in the recent years, their market share in volume has increased from 17% in 2009 to a mere 24,5% in 2021 [27, 53].

Issues of concern

Greece's low generics penetration

After a decade of reforms in the pharmaceutical sector it is evident that pricing as a standalone measure failed to increase the penetration of generics. This target remains unattainable due to a series of reasons:

- Negative perception for generics by health professionals, patients, and the public.
- Low price sensitivity for the patients due to the copayment system not sufficiently incentivizing the use of cheaper alternatives. This is enhanced by the overall low-price level of medicines.
- The pharmacy margin structure incentivizes the dispense of the more expensive medicines i.e. The retail margin's structure is inversely proportional, however the vast majority (~80%) of the reimbursed products dispensed from the pharmacy are priced up to 50 € corresponding to 30% margin. That, results to the pharmacist (if not limited otherwise by the physician) being actually incentivized to choose a product that costs e.g., 49.9 € rather than a cheaper alternative.
- Lack of policy measures e.g., restrictive prescription protocols to tackle the unjustified switching towards new expensive medicines which remain the main driver for the overspending.
- Price decreases for generics should be considered within the framework of a comprehensive pharmaceutical policy capturing their full potential to produce savings

9.7 Other cost-containment measures

An electronic tracking system has been introduced since May 2013, which should help the EOF to trace the movement of pharmaceuticals along the entire distribution chain and is designed to make it more difficult for wholesalers to illegally export Greek drugs [54]. The system monitors all pharmaceutical products in circulation along the entire distribution chain based on the unique serial number of each medicine authenticity tape that must be attached to every package of medicine. In parallel, Greece is endeavoring towards the setting of the new coding and serialization system according to the FMD Directive, which is expected to be fully operational in 2023.

Since 2010, procurement of pharmaceuticals and medical devices by public hospitals is being performed by the Health Procurement Committee (EPY). Under the new centralized procurement system and by unifying the annual tenders, EPY's remit is to control and reduce procurement costs, normalize payment time, make uniform requests for health supplies, and reduce waste of resources by transferring redundant materials between hospitals, and improving management of expired products [55]. In mid-2017, the EPY was replaced by the National Central Authority of Health Procurements (EKAPY) while the Price List Observatory was replaced by the Registry of

Highest Acceptable Prices Observatory to improve centralized procurement and cost reduction [49]. The scope of the new authority includes all healthcare units under the jurisdiction of the Ministries of Health, Defense (e.g., military hospitals) and Education (e.g.,. university hospitals). An important policy target is increasing the share of generics in terms of volume of all medicines prescribed/used in public hospitals to 50%, though this goal has not yet been achieved [45].

Issues of concern

The distortion of clawback

- Clawback mechanism allows the government to underspend on healthcare while creating an unsustainable economic environment especially for generics companies. Extreme pricing pressures, combined with devastating clawback along with the relatively small market size which does not allow for economies of scale, create an impossible operating environment for generics companies, which are often obliged to withdraw from the market, products that lack a viable outlook.
- Notably, between 2014-2019, 1,739 generics were withdrawn from the market. i.e., 42.6% of all generic products present at the positive list of July 2014. During the same period, 1,232 generics were introduced, so the positive list of July 2019 includes 505 less generics than the 2014 list. This is a continuing trend.
- Although the industry provides at ex-f prices, the clawback is calculated on the retail price level, including the profit of the supply chain i.e., the industry pays the corresponding paybacks.

9.8 Conclusions

The European pharmaceutical systems in the Central Eastern and Southern European region are at a cross road of reforms, and Greece represents a good example of both success and failures of pharmaceutical policies. The economic crisis has introduced a new impetus in balancing the economic and social objectives in the pharmaceutical systems. The decline in GDP and the corresponding reduction in pharmaceutical expenditures have jeopardised the ability of EU governments to satisfy the Lisbon's Strategy objectives of equity, efficiency, and effectiveness.

Even before the crisis, the Greek healthcare system was afflicted with a plethora of structural weaknesses. The long-standing waste of resources has been replaced by a serious underfinancing during the crisis, and the already undermined public health system has sustained a further quality deterioration. In the short to medium term, the pharmaceutical and the public healthcare sector in general will continue to come under enormous strain due to a lack of adequate funding and increasing demand from citizens unable to afford to pay for pharmaceutical services. The under-financing and the increasing unmet medical needs may induce a one de facto two-tiered health system, which is split between those patients who can afford pharmaceutical care and meet their

healthcare needs, and the economically vulnerable individuals who can only access necessary health services from a severely strained public healthcare system

The recently enacted legislation on January 17th 2018 established a HTA process, based on a committee, and not an independent Institution. The current pricing and reimbursement system appears to be highly centralized without considering the overall international experience introduced by the EUnetHTA and other corresponding European organizations like the NICE in U.K. or the IQWIG in Germany. Greece is challenged to meet the objectives of a transparent, equitable, and sustainable health system, and further improvements are still needed to fulfil these long anticipated social and economic targets, especially with respect to an autonomous, transparent, and effective HTA mechanism.

KEY ISSUES FOR PHARMACEUTICAL POLICIES

- Pricing as a cost-control tool must be used with caution since it may undermine the sustainability of the products. Furthermore, pricing pressure, if not combined with a coherent policy to monitor and control prescribing and use of medicines, may result to high rates of switching towards more expensive alternatives and consequently to the increase of expenditure.
- The gradual decrease of the annual budget targets to converge with the EU average, followed a top-down approach, however with little consideration of the patient needs and of the peculiarities, the weaknesses, and the inefficiencies of the Greek health system e.g., the fragmentation of primary health, the lack of sustainable cost-control administrative tools, cultural and societal parameters regarding the use of medicines.
- The insufficiently low level of the budget limit, the extension of the covered population with the inclusion of the uninsured population, the introduction of new costly medicines, and the lack of demand side measures to control the cost and promote the rational use of medicines, led to the escalation of clawback to record high levels among the EU countries.
- The establishment of electronic prescribing system is considered as the most significant reform implemented so far. However, there is still room for improvement i.e., the extension of e-prescribing at the hospitals, the inclusion of biding therapeutic protocols, the use of e-prescription data to support policy decisions, the integration of prescribing with the e-diagnostic system and ultimately with the electronic patient record.
- It is worth mentioning that the update of the e prescribing system is a main feature of the Greek RRF program for health allowing Greece to converge with the other EU countries that already have successfully implemented relevant e-prescribing systems.
- The establishment of the HTA and Negotiation committees certainly had a positive impact in cost controlling and rationalization of reimbursement. Notably, until recently Greece was the only EU country lacking such expenditure control mechanisms. However, the development of the HTA and Negotiations committees into a full independent HTA body remains a challenge.
- Clawback remains the most important challenge for the Greek public pharmaceutical care sector, due to both its height which is unique among the EU and its allocation method whereby the budget excess, and therefore the clawback, created by the cost of new medicines was allocated to all reimbursed products present in the market. This distortion, combined with the pricing pressures created an impossible environment especially for generics and economic affordable products.
- After a series of reforms regarding the clawback allocation, the recent (2022) split of the total budget into two distinguished sub-budgets, i.e., one for the high-cost medicines and one for the retail products provided by community pharmacies, each with its own clawback, is expected to improve its fairness.

- The Negotiation Committee has the mandate to cast agreements with the relevant MAHs on ATC 5 or ATC4 level, thus increasing the fairness of the clawback whereby each MAH would be penalized only for the excess that he creates within the agreement.
- The RRF program for health introduced a co-responsibility clause, whereby if the clawback exceeds a certain level, then a contribution by the state would be enacted. This is of great importance as it is expected to further incentivize the government to intensify its effort to reduce/ control the total clawback.

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