THE PHARMACEUTICAL MARKET IN GREECE

FACTS & FIGURES



2020



FOUNDATION FOR ECONOMIC & INDUSTRIAL RESEARCH

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Contents

	Executive Summary	
1	Economic environment	
	1.1 Pandemic – Macroeconomic environment	
	1.2 Pandemic control measures	
2	Demographic trends and health profile of the population	
	2.1 Natural population change	
	2.2 Life Expectancy	
	2.3 Ageing Population	
	2.4 Dependency ratio	
	2.5 Causes of death-Chronic diseases-prevention	
3	Demand side: Health and pharmaceutical expenditure	
	3.1 Funding on health expenditure	
	3.2 Pharmaceutical Expenditure	
	3.3 Patients' Contribution	
4	Supply side: Pharmaceutical Industry and Economy	
	4.1 Supply chain for pharmaceutical products in Greece	
	4.2 Research and development (R&D)	
	4.3 Production	
	4.4 Employment	
	4.5 Sales	71
	4.6 External trade	
5	State's outstanding debts towards pharmaceutical companies	
6	Appendix	
	6.1 System of Health Accounts (SHA)	
	6.2 Pharmaceutical expenditure-Sales	

List of Figures

Figure 1: Cases and Deaths due to COVID-19 in EU countries	. 13
Figure 2: Additional deaths due to COVID-19	. 14
Figure 3: ICU beds per 100,000 people (before COVID-19)	. 16
Figure 4: Total available beds and ICU beds for COVID-19 (2020), Greece	. 17
Figure 5: Number of Doctors and Nurses per 1,000 people, 2018	. 17
Figure 6: GDP components (€) and annual change (%) - Greece	. 18
Figure 7: GDP development by country	. 19
Figure 8: General Government Balance & Current Account Balance (% GDP)	20
Figure 9: General Government balance (% GDP)	. 21
Figure 10: Unemployment rate (% of total population) Greece-EU27-Southern countries	. 22
Figure 11: Natural change of population (thousand people)-Greece	. 29
Figure 12: Evolution of life expectancy at birth (years) in Greece-OECD	. 30
Figure 13: Life expectancy at birth (years) Greece-EU27-Southern countries (2018)	. 31
Figure 14: Population aged 65 and above (% total population) Greece-EU27	. 32
Figure 15: Ageing Index of population in Greece	. 33
Figure 16: Causes of death (% of total deaths) – Greece (2018)	. 34
Figure 17: Percentage of population suffering from chronic health problem or chronic disease, 2019	. 35
Figure 18: Prevention expenditure per capita, Greece-EU23 (2018)	. 35
Figure 19: Total and public health expenditure (bil.€)	. 36
Figure 20: Index of cumulative change on health expenditure (%) Greece-EU23-Southern countries	. 37
Figure 21: Total health expenditure (% GDP) Greece-EU23-Southern countries	. 38
Figure 22: Public health expenditure (% GDP) Greece-EU23-Southern countries	. 39
Figure 23: Public health expenditure (% of total expenditure) Greece-EU23-Southern countries	40
Figure 24: Total per capita health expenditure Greece-EU23-Southern countries	. 41
Figure 25: Average per capita health expenditure evolution, OECD counties, 2008-2013 and 2013-2019	. 42
Figure 26: Health expenditure of households (€) per month-Greece	43

THE PHARMACEUTICAL MARKET IN GREECE:

FACTS & FIGURES 2020

Figure 27: Breakdown of household health expenditure (%) per month - Greece	
Figure 28: Total expenditure for pharmaceuticals and other medical non-durable goods (bil. €)-Greece	
Figure 29: Public per capita expenditure for pharmaceuticals and other medical non-durable goods Greece-EU22-Southern countries	46
Figure 30: Public & private per capita expenditure for pharmaceuticals and other medical non-durable goods (2018)	
Figure 31: Public expenditure for pharmaceuticals and other medical non-durable goods (% GDP) Greece-EU22-Southern countrie	48
Figure 32: Public Outpatient pharmaceutical expenditure and industry's contribution (excluding patients' contribution)	49
Figure 33: Total outpatient pharmaceutical expenditure	50
Figure 34: Public hospital pharmaceutical expenditure and industry's contribution	51
Figure 35: Patient participation in the reimbursement market (2020)	53
Figure 36: Total private pharmaceutical expenditure (2020))	
Figure 37: Number of pharmacies per 100.000 inhabitants EU27 (2019)	56
Figure 38: Pharmacies and wholesalers- Greece	57
Figure 39: Pharmacies EU27-Greece (2019)	58
Figure 40: Total number of clinical trials, all phases and stages (2002-2020)	60
Figure 41: Pharmaceutical R&D expenditure (% of total R&D expenditure) (2017)	61
Figure 42: Number of clinical trials by phase and year	61
Figure 43: Production of pharmaceutical products (mil.€)	62
Figure 44: Industrial index of domestic pharmaceutical production (2015=100)	63
Figure 45: Turnover index in domestic pharmaceutical production (2015=100)	64
Figure 46: Gross Value Added of pharmaceutical production and share in manufacturing (%)	65
Figure 47: Percentage of pharmaceutical production in Greece and abroad (in market volume)	66
Figure 48: Employment in pharmaceutical production (thousand people)	67
Figure 49: Number of employees with tertiary education in pharmaceutical production (%)	68
Figure 50: Employment in the production of pharmaceutical products (% shares) (2019)	69
Figure 51: Sales of pharmaceutical products in values (bil.€)-Greece	71
Figure 52: Sales of pharmaceutical products in volume (mil. packages) - Greece	

Figure 53: Penetration of pharmaceuticals in EU18, 2020 (in volume) based on patent status	73
Figure 54: Pricing of pharmaceuticals in EU18, 2020 (price per unit.€) based on patent status	74
Figure 55: Share of generics -Greece value-volume (2012-2019)	75
Figure 56: OTC sales in value (in mil. ϵ)	76
Figure 57: Evolution of pharmaceutical trade balance (mil.€)	77
Figure 58: Share of pharmaceutical exports-imports (% of total exports-imports)-Greece	78
Figure 59: Parallel exports (in values) 2008-2019	80
Figure 60: Annual change (%) of HCIP by category (2015=100)	84
Figure 61: State debts evolution towards SfEE member companies' until per year (€ mil.)	87

List of Tables

Table 1: Basic data	. 14
Table 2: Financial support from the SURE program	26
Table 3: Allocation of EU funds	28
Table 4: Change in employment and wages 2012-2019	70
Table 5: Sales self-medication products (mil.€)	76
Table 6: Exports of medicines by country (2020)	79
Table 7: Pricing system	81
Table 8: Mark-up in the pharmaceutical supply chain	83
Table 9: Percentage of profit (mark-up) pharmacies	. 83



The report "The Pharmaceutical Market in Greece: Facts & Figures 2020" was produced by research staff of IOBE with the cooperation of SfEE.

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"THE PHARMACEUTICAL MARKET IN GREECE: FACTS & FIGURES 2020"

It is with great pleasure to preface the renewed annual edition 'The Pharmaceutical Market in Greece: Facts & Figures 2020', produced by research staff of IOBE in collaboration with SfEE.

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

More specifically, this year's edition attempt to include all data available until the end of 2020 and to present an updated profile of the pharmaceutical market and the main changes that occurred.

This year's edition takes place in the shadow of the COVID 19 pandemic, an unprecedented crisis for the world, which underscored the definite importance of the discovery. development and access to new diagnostics, new treatments and vaccines to tackle global health threats. It is now clear that the answer to this kind of health crises is innovation and rapid development of diagnostics, therapeutic s and vaccines.

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

We would like to thank the IOBE and SfEE research staff

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EXECUTIVE SUMMARY

The coronavirus pandemic (COVID-19) caused significant challenges in many countries around the world in 2020, while these continue in 2021. In addition to the loss of human life, the large number of patients and the big pressure on health systems, in some countries, there is also an economic crisis due to the interruption or reduction of economic activity in many sectors. The partial or general lockdown is expected to sink the economies for 2020, including the Greek economy. In any case, it is universally accepted that the coronavirus crisis will cause a significant economic decline in the Greek economy (recession -8.2%), but also in other developed and industrialized countries. At the same time, European health systems must reassess public health expenditure.

To tackle the pandemic, the European Commission, in cooperation with the Member States, has taken short - term but long - term decisions to protect the health and wealth of EU citizens and to save human lives. To support research, mainly on vaccines and coronavirus treatment since January 2020, the European Commission has directed more than €660 million under the Horizon 2020 program to develop vaccines, new therapies, diagnostic tests and medical systems to prevent the spread of the coronavirus and save human lives. At the financial level, and in the first phase, the temporary support program SURE (temporary Support to mitigate Unemployment Risks in an Emergency - SURE) was activated, to keep employment in the Member States.

The **demographic trends** also directly affect the population's ageing and dependency ratio. In Greece nearly half of the population is dependent on the other half, and its proportion is expected to growth, signaling increased pressure on the social security system. In 2020, Greece's dependency ratio reaches 56%, meaning that for every 2 active people there is 1 inactive, close to EU27 average (56%) and the average of Southern countries (55%).Over time, there has been a strong rise in the number of deaths in Greece due to circulatory system diseases in 2017 accounted for 37.7% of total deaths, while the number of deaths due to neoplasms estimated at 24.6% of total deaths.

Total health expenditure decreased by -33.7% during the period 2010-2019 (+ 1.7% in Southern countries, +17.0% in the EU), amounted at €14.4 bil. in 2019 (7.8% of GDP). **Public health expenditure** decreased by -42.5% (-4.5% in Southern countries, + 17.4% in the EU) over the same period, amounted at €8.6 bil. in 2019 (4.5 % of GDP). The decline in public health expenditure has resulted in a shift in health spending to the private sector, with private health expenditure reaching 40.8% in 2019 (28.1% in Southern countries, 20.4% in the EU).

However, the needs of the population for health care are affected, amongst others, by demographic trends: life expectancy in Greece is high (81.9 years higher than EU average 81.0 years in 2018),

steady reduction of the population (births - deaths) by -34,000 people (2019), and increased ageing population (over 65) from 22.3% of the total population in 2020 rising to 33.5% in 2060.

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

With regards to the pharmaceutical expenditure, **total outpatient pharmaceutical expenditure** in Greece estimated at €3.9 bil. in 2020, (€2,0 bil. is public pharmaceutical expenditure), while **public outpatient pharmaceutical expenditure** decreased by -60.8% over the period 2009-2020. At the same time the weight shifted towards private sector, with industry's contribution, through flat mandatory returns and discounts (rebate and clawback). As far as public hospital pharmaceutical expenditure is concerned during the period 2012-2015 amounted to €760 mil. From 2016 onwards, with the introduction of closed budget, it was significantly reduced by -18%, resulting in the contribution of pharmaceutical industry with €598 mil. in 2020.

The significant reduction in the public sector's contribution to pharmaceutical spending has resulted in a shift to the private sector where for 2020 **patient participation** in outpatient pharmaceutical expenditure reaches around €636 mil. and industry in €1.3 bil., while in hospital pharmaceutical expenditure the participation of the industry reaches to €483 mil. As a result, the industry for 2020 with rebate and clawback mechanisms has reached the needs of Greek patients for pharmaceutical coverage with 1 out of 3 medicines (33%) in out-patient and 1 in 2 medicines (50%) at hospital level.

Despite the significant impact of fiscal adjustment on public funding, the pharmaceutical industry remains a pillar for investment in Greece with Research and Development (R&D) expenditure close to 5% of total R&D expenditure in Greece (2017) and 3,114 clinical studies independent of phase and stage conducted the period 2002-2020 (1,800 completed). Production of pharmaceutical products in Greece was estimated at \leq 1.4 bil., with Gross Value Added (ex-factory) at \leq 1.2 bil. (6.6% of the manufacturing). Employment in the manufacturing of pharmaceutical products in Greece was estimated at 23.1 thousand people in 2020, with 57.1% of them with university education, compared to 36.7% of the total economy and 23.1% of the total manufacturing.

Lastly, imports and exports of pharmaceutical products amounted to €4.7 bil. and €2.9 bil., respectively in 2020 and accounted for 9.4% of total Greek exports in 2020.

ECONOMIC ENVIRONMENT

Greece, like the rest of the world, faced with a unique threat in 2020, as the outbreak of the pandemic COVID-19 caused a severe health problem, while at the same time reducing economic activity, with pressure on demand and supply of the economy. At European level, health and economic measures have been taken, both in the short and long term, to tackle the pandemic. In the economic part, and in the first phase, the temporary support programme SURE (temporary Support to mitigate Unemployment Risks in an Emergency - SURE) was activated, to restrain employment in the Member States. In addition, the general escape clause of the Stability and Growth Pact was activated, so that countries have the necessary fiscal space to support their economies. The category of short-term measures also includes the Recovery Fund (Next Generation European Union - NGEU), while the medium-long-term measures include the transformation of the new Programming Period 2021-2027, ie the new Partnership Agreement, for which the initial objectives apply (before the pandemic), but The European Commission is aiming for the distribution of funds to deal with the pandemic. In addition to the fiscal instruments that will be activated, the European Central Bank (ECB) is supporting the eurozone economy with liquidity-enhancing measures.

1.1 PANDEMIC – MACROECONOMIC ENVIRONMENT

The COVID-19 pandemic that marked 2020, affected almost all the world's economies, causing a large number of deaths and hospitalizations, great pressure on health systems and serious effects on the economy, creating an unknown situation for EU countries and European Commission. The cases at the end of 2020 amounted to 20 million, and deaths to 465 thousand in EU countries¹. The cases per million people are very high in Luxembourg and the Czech Republic, while Greece was quite low, 2nd from the end, with 13.6 thousand cases per million people. Covid deaths are around 1,716 per million people in Belgium, first among EU countries, followed by Slovenia and Italy. Greece records 489 deaths per million people, in lower positions.

¹ Last Updated January 8, 2021

Economic environment

Figure 1: Cases and Deaths due to COVID-19 in EU countries

Cases (per million people)

Luxembourg

Czechia

Slovenia

Lithuania

Belgium

Croatia

Sweden

Portugal

Spain

Austria

France

Slovakia

Poland

Hungary

Romania

Denmark

Bulgaria

Ireland

Latvia

Estonia

Cyprus

Greece

Finland

Germany

Malta

Italy

UK

Netherlands





The excess mortality in each country compared to previous years, attributed to the pandemic. Spain and Italy recorded many additional deaths, with an 50% increase in March 2020, while Greece shows a relatively limited deviation from the trend of previous years.



Greece has a relatively low number of cases per million people (13 thousand) compared to Southern countries, also Germany and France, but has the lowest number of tests per 1,000 people. Covid deaths per million people (464.2), are at a higher level than Cyprus and Germany, but clearly lower than Italy and Spain and Portugal. ICU patients are close to the levels of other countries, while in terms of the severity of the measures, Greece in December follows a rather strict framework of measures.

Table 1: Basic data

Country	Greece	Cyprus	France	Germany	Italy	Portugal	Spain
Cases (per million people)	13.321	25.139	41.022	21.013	34.851	40.570	41.242
Deaths (per million people)	464,2	135,9	992,1	403,3	1.226,5	677,3	1.087,3
Intensive Care Unit patients (per million people)	42,0	30,8	40,2	67,1	42,3	47,3	43,2
Tests (per 1.000 people)	268,9	1.184,6	-	-	439,9	557,2	484,7
Stringency index (100=stricter)	84,3	74,1	63,9	82,4	88,0	-	78,7
Population density	83,5	127,7	122,6	237,0	205,9	112,4	93,1
Population over 70 years old (% total population)	14,5	8,6	13,1	16,0	16,2	14,9	13,8
GDP per capita (\$, 2011 prices)	24.574	32.415	38.606	45.229	35.220	27.937	34.272
Cardiovasc death rate (per million people)	17,6	14,1	8,6	15,6	11,3	12,8	9,9
Female smokers (%)	35,3	19,6	30,1	28,2	19,8	16,3	27,4
Male smokers (%)	52,0	52,7	35,6	33,1	27,8	30,0	31,4
Hospital Beds (per 1.000 people)	4,2	3,4	6,0	8,0	3,2	3,4	3,0
Life expectancy	82,2	81,0	82,7	81,3	83,5	82,1	83,6

SOURCE: Our World in Data, (data until 31/12/2020)

At the beginning of the pandemic, Greece had a few Intensive Care Units (ICU beds), 5.3 per 100 thousand people, in the lowest positions among European countries, and below half of the European average (12.9).



By the end of 2020, there are a total of 6,064 beds in the country for the treatment of confirmed cases of COVID-19. There are also 1,203 ICU beds, of which 579 are non-COVID ICUs and 624 are ICU-COVID beds.



Figure 4: Total available beds and ICU beds for COVID-19 (2020), Greece

Greece still has the highest density of doctors (6.1 per 1,000 people) and the lowest density of nurses (3.4 per 1,000) among EU countries for 2018.



Figure 5: Number of Doctors and Nurses per 1,000 people, 2018

In economic terms, the pandemic caused change in the growth pace that had been created since 2017 in the Greek economy, estimating that Gross Domestic Product (GDP) will shrink by 9.0% in 2020, with a strong impact from falling exports and private consumption. According to the European Commission forecasts, the 2021 recovery is expected to partially offset the losses created in 2020, with exports as the main driver, while in 2022 GDP will fall slightly below 2019 levels.



Figure 6: GDP components (€) and annual change (%) - Greece

SOURCE: ELSTAT 2021, AMECO 2020 (last update 5 November 2020), data processing IOBE

Based on the data available, GDP shrank by 13.8% in the second quarter of the year and -10.5% in the third quarter, while a relative de-escalation was recorded in the last quarter with a recession of 7.9%. In 2020 the recession was -8.2%, while from the sub-sectors of the Greek economy a significant decline was recorded in the broader sector of Arts and Leisure with 24% recession, but also in the sector of Trade, Transport, Accommodation and Catering with decline by 22%. On the other hand, an increase of 16.6% was recorded in the economic activity of Construction. The

contraction of GDP in the second quarter in Greece was at the level of other countries, while due to dependence on tourism, an industry that was hit hard by the pandemic, the Greek economy shrank more in the third quarter of the year (-11.7%), compared to several countries and the EU27 average (-4.2%).



The solid fiscal base that the Greek economy had managed to create by 2019, after the adjustment programs, is reversed in 2020, in the context of the need to support the economy by increasing public spending and reducing taxes. The general escape clause of the Stability and Growth Pact was activated, which has allowed the increase of public expenditures and the creation of budget deficits, while in the external sector a deterioration is also expected, with the current account deficit estimated at -6.2%. GDP, compared to a deficit of -1.5% in 2019. For 2021 and 2022, it is estimated that fiscal figures will improve, without returning to a positive sign.



Figure 8: General Government Balance & Current Account Balance (% GDP)

SOURCE: ELSTAT. 2020, AMECO 2020, data processing IOBE. The government budget deficit also includes interest on debt repayment but does not include extraordinary entries in revenues and expenses due to the recapitalization of banks. The external sector balance is reported in the current account balance and includes the balances of goods and Services, Primary Income (Labour, Entrepreneurship) and Secondary Income (Current Transfers), general government Balance does not include the impact of the support to the financial institutions from all interventions during the financial crisis on the general government deficit.

The state budget deficit stood at 5.8% of GDP in the first quarter of 2020, while in the second quarter it escalated to 12.1%, slightly higher than the EU27 average (-11%). The deficit widened significantly in Spain (-24.6%), while in Italy and Portugal the deficit approached -10% in the second quarter of 2020, in an effort by countries to support industries and jobs. In Greece, the EU average, but also in Spain and Portugal, the deficit was corrected in the third quarter of 2020, while in Italy it remained quite high. It is noted, however, that in Greece the fiscal deviation is greater, as the starting point of 2019 was high surpluses.

Figure 9: General Government balance (% GDP)



SOURCE: Eurostat

The gradual reduction of unemployment rates was stopped in 2020 in Greece but also in Europe, with an increase in the unemployment rate to 18.0% for Greece, compared to 17.3% in 2019, maintaining the highest rate among EU countries. The Southern countries are also expected to show a higher unemployment rate in 2020, with a further increase in 2021. The data for 2020 for Greece show an increase in the unemployment rate in May and June, while in the remaining months there was a shift in the workforce to the inactive population, resulting in reduced unemployment rates.



Figure 10: Unemployment rate (% of total population) Greece-EU27-Southern countries

SOURCE: Eurostat, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal)

At the same time, in 2019 a high rate of long-term unemployment is recorded at 70.1% of the total unemployed, that is 574.3 thousand people remain out of the labour market for more than 12 months. The highest unemployment rate is found among young people aged 15-24, while in absolute numbers the largest number of unemployed comes from ages 25-49, the most productive age group, with about 550.1 thousand people unemployed.

1.2 PANDEMIC CONTROL MEASURES

To tackle the pandemic, the European Commission, in cooperation with the Member States, has taken short-term but also long-term decisions to protect the health and well-being of EU citizens and to save lives. The EU's response to the COVID-19 pandemic focuses on four priorities:

- limiting the spread of the virus
- ensuring the provision of medical equipment
- promoting research on treatments and vaccines
- support for employment, business and the economy

Public Health

In 28th May 2020, the Commission has proposed a powerful, modern new EU programme in the area of health for the period 2021-2027, the EU4Health. This programme is a strong response to the COVID-19 pandemic, but also maintains a focus on long-term EU actions in the health field. It aims to improve public health in the EU and make the Union better prepared to cope with future health crises.

In accordance with the results of the European Council meeting of 17-21 July 2020, the budget proposed in the Council mandate of EUR 1.9 billion is four times the size of the budget of the current programme for 2014-2020.

The EU4Health programme aims to complement the national policies of the member states and to promote coordination between them in order to improve human health throughout the Union by:

- protecting people in the Union from serious cross-border threats to health
- improving availability of health products and crisis relevant products
- strengthening the resilience and sustainability of health systems
- increasing the use of digital tools and services in the health area
- strengthening the role of the European Union in global health

The Council reached an agreement on the EU4Health program on 21 October 2020.

On 11 November 2020, the Commission laid the first bricks of a European Health Union, based on two pillars:

- A stronger health security framework,
- More robust EU agencies

The **first pillar** refers to harmonising European, national, and regional preparedness and response plans. These plans would be stress-tested and audited regularly by the Commission and EU agencies. Additionally, an EU emergency system it would trigger increased coordination and rapid action to develop, stockpile, and procure the equipment needed to face the crisis.

The second pillar entails:

- The European Centre for Disease Prevention and Control will monitor the epidemiological situation based on common data.
- The European Medicines Agency's mandate will cover the safety of medicines and medical devices, risk of shortages and clinical trials of medicines.
- A new Health Emergency Response Authority (HERA) will be created.

Funding research for vaccines, treatment, diagnostic tests

The Commission has mobilised more than €660 million under Horizon 2020 since January 2020 to develop vaccines, new treatments, diagnostic tests, and medical systems to prevent the spread of the coronavirus and save lives. The EIB financing is backed by both Horizon 2020 and the Investment Plan for Europe.

The European Commission has been negotiating intensely to build a diversified portfolio of vaccines for EU citizens. Contracts have been concluded with 6 promising vaccine developers, securing a portfolio of up to 4.4 billion doses. Deliveries of vaccine doses to European Union countries have increased steadily since December 2020. Vaccination gathers pace across the European Union. The Commission has so far given 4 conditional marketing authorisations for the vaccines developed by BioNTech and Pfizer, Moderna, AstraZeneca and Janssen Pharmaceutica NV following EMA positive assessment of their safety and efficacy. Several other vaccines are at different stages of assessment by the European Medicines Agency (EMA).

Company	Type of vaccine	Number of doses (needed per person)	Number of doses (secured))	Status
BioNTech and Pfizer	mRNA	2 doses	2.4 billion	Approved
Moderna	mRNA	2 doses	460 million	Approved
CureVac	mRNA	2 doses	405 million	Development ongoing
AstraZeneca	adenovirus	2 doses	400 million	Approved
Johnson & Johnson/Janssen Pharmaceuticals	adenovirus	1 dose	400 million	Approved
Sanofi-GSK	protein	2 doses	300 million	Development ongoing
SOURCE: European Commission				

The Commission has also concluded exploratory talks with Novavax with a view to purchasing up to 200 million doses, and Valneva with a view to purchase up to 60 million doses.

Greece, in the initial design, will gradually supply vaccines from at least six (6) producers, starting with the first receipt in December 2020 from Pfizer / BioNTech.

Economy

The temporary Support to mitigate Unemployment Risks in an Emergency (SURE) is available for Member States that need to mobilise significant financial means to fight the negative economic and social consequences of the coronavirus outbreak on their territory.

EU adopted, a temporary scheme which can provide loans under favourable terms to member states. The instrument enables member states to request EU financial support to help finance the sudden and severe increases of national public expenditure, related to national short-time work schemes and similar measures, including for self-employed persons, or to some health-related measures, in particular at the work place in response to the crisis.

Until October 2020, EU provided €87,9 bil. for 17 member states. Portugal was at the top of the list with €5.9 bil. while Greece absorbed €2,7 bil., corresponding to 1.6% of the GDP.

Country	million €	% GDP
Portugal	5,900	3.0%
Slovenia	1,100	2.4%
Cyprus	479	2.3%
Poland	11,200	2.2%
Croatia	1,000	2.1%
Malta	244	2.0%
Spain	21,300	1.9%
Romania	4,100	1.9%
Belgium	7,800	1.8%
Italy	27,400	1.7%
Greece	2,700	1.6%
Lithuania	602	1.2%
Czechia	2,000	1.0%
Bulgaria	511	0.9%
Slovakia	631	0.7%
Latvia	193	0.7%
Hungary	504	0.4%

Table 2: Financial support from the SURE program

SOURCE: European Commission

In addition, for 2020 at least, the general escape clause of the Stability and Growth Pact was activated, so that countries have the necessary fiscal space to support their economies. However, it is estimated that the crisis will have a structural impact on economies and businesses, leading to short- and medium-term stimulus measures. The first category of short-term measures includes the Next Generation EU with funds of \in 750 billion, while the medium-term measures include the transformation of the new Programming Period 2021-2027, ie the new ESPA, for which the initial objectives apply (before the pandemic) but the European Commission aims to provide forward disbursement of funds to address the pandemic.

EU's extraordinary recovery effort, (NGEU – Next Generation EU) will consist of \in 390 billion in grants to the States and another \in 360 billion in loans. The objectives of the fund concern:

- 1. The promotion of economic, social and regional cohesion
- 2. Enhancing economic and social resilience
- 3. Addressing the economic and social consequences of the health crisis
- 4. The digital and "green" transition

The resources that will be allocated to Greece by the Recovery Fund and which concern the response to the crisis triggered by the COVID-19 pandemic are about \in 32 billion, \in 19.5 as grants and the rest as loans. This money will have to be absorbed over a period of six years, while the development plan can only be revised once in 2022. By then, 70% of the total \in 32 billion should have been contracted, while the same process for the remaining 30% should be completed next year.



EU's multiannual financial framework (MFF) 2021-2027 package 1,1 tril., includes:

- "a smarter Europe by promoting innovative and smart economic transformation"
- "a greener, low-carbon Europe by promoting clean and fair energy transition, green and blue investment, the circular economy, climate adaptation and risk prevention and management"
- "a more connected Europe by enhancing mobility and regional ICT connectivity",
- "a more social Europe implementing the European Pillar of Social Rights"
- "a Europe closer to citizens by fostering the sustainable and integrated development of urban, rural and coastal areas and local initiatives".

	MFF	NGEU	total
1. Single market, innovation and digital economy	132,8	10,6	143,4
2. Coherence, resilience and values	377,8	721,9	1.099,7
3. Natural resources and environment	356,4	17,5	373,9
4. Immigration and border management	22,7		22,7
5. Security and defense	13,2		13,2
6. Neighboring countries and the rest of the world	98,4		98,4
7. European public administration	73,1		73,1
Total	1.074,4	750,0	1.824,4

Table 3: Allocation of EU funds

SOURCE: European Commission, EU's multiannual financial framework (MFF) 2021-2027, NGEU - Next Generation EU

Finally, the European Central Bank (ECB) has already made announcements since the beginning of the pandemic to support the economies and banks, with measures that affect the entire European economy and especially the Greek economy. The 1,850 billion pandemic emergency purchase program (PEPP) which has been implemented, also includes Greek bonds. The easing of the conditions for the integration of Greek bonds is estimated to have stabilized the markets and deescalated the country's lending rates. In addition, the ECB has eased the conditions under which it provides liquidity to banks, promoting longer-term lending, strengthening the incentives to extend bank lending to the real economy.

2.1 NATURAL POPULATION CHANGE

The number of births in Greece amounted to 83.7 thousand people in 2019 recording a 3.1% decrease from previous year, while the number of deaths recorded an increase of 3.9%, amounting to 124.9 thousand people. As such, the natural population change (difference births - deaths) result in an overall reduction of -41.2 thousand people in 2019.



SOURCE: ELSTAT., 2020 *Natural change is defined as the change due only to the difference in births - deaths without taking into account immigration ** The number of births does not include stillbirths, which in 2019 amounted to 454

2.2 LIFE EXPECTANCY

The technological advances, improvement in the provision of healthcare services, contribution of R&D and introduction of innovative new drugs and therapies partially are some of the most important factors explaining the increase of life expectancy. Life expectancy in Greece has increased considerably by 9.4 years during 1960-2017 and it is higher than the average of OECD countries in the same period.



Figure 12: Evolution of life expectancy at birth (years) in Greece-OECD

SOURCE: OECD, Health Statistics 2020

2.3 AGEING POPULATION

Life expectancy in Greece reached 81.9 years in 2018, which is higher from EU27 average (81.0 years) and lower than in Southern countries (83.3 years). The highest life expectancy was recorded in Spain, and Italy.



SOURCE: OECD, Statistics 2020, Eurostat 2019, data processing IOBE *Southern countries (Italy, Spain, Portugal)

Based on the latest revision from Eurostat, the steady decline of the population is expected to continue until 2060 (-15.5% in comparison to 2020 data). The percentage of people aged 65 and above in Greece is expected to increase from 22.3% of the total population in 2020 (20.6% in EU27) to reach 33.5% in 2060.



SOURCE: Eurostat, Population Projections, 2020, data processing IOBE *Not included the possible legalization of migration from 2015 onwards

2.4 DEPENDENCY RATIO

The demographic changes directly affect population's dependency ratio. In Greece, nearly half of the population is dependent on the other half, and this proportion is expected to grow, signaling deterioration and increased pressure on the social security system. In 2020, Greece's dependency ratio reaches 56%, meaning that for every 2 active people there is 1 inactive, close to EU27 average (56%) and close to the average of Southern countries (55%). According to the United Nations, the dependency ratio in Greece is estimated to reach 92% by 2050.

The ageing index is the ratio of people aged 0-14 years to people aged 65 years, ie it reflects the proportion of older people in every 100 children (Ageing Index = $100 \times [N65 + / (The increase in the index can be due either to an increase in the elderly or to a decrease in births.$



Figure 15: Ageing Index of population in Greece

SOURCE: ELSTAT. 2020, data processing IOBE

2.5 CAUSES OF DEATH-CHRONIC DISEASES-PREVENTION

Over time, a significant increase in the deaths due to circulatory system diseases is recorded, responsible for 37,1% of total deaths, despite the decline in recent years, while increase in neoplasms is recorded, accounting for 25.2% of total deaths. Interestingly, the increase in the share of diseases of the respiratory system after 2009, after a stabilization period, and finally the violent deaths and infectious and parasitic diseases compose a small part of the total deaths.



SOURCE: ELSTAT, 2020 data processing IOBE *Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-10) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations. Other causes: Diseases of the digestive system, Diseases of the genitourinary system, Diseases of the nervous system and sense organs, Endocrine and metabolic diseases, nutrional deficiencies and immune disorders

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



Figure 17: Percentage of population suffering from chronic health problem or chronic

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



Figure 18: Prevention expenditure per capita, Greece-EU23 (2018)

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

SOURCE: OECD, Health Statistics 2020

3.1 FUNDING ON HEALTH EXPENDITURE

In 2019, total health expenditure in Greece amounted to \in 14.6 bil., out of which \in 8.7 bil. composes public health expenditure and \in 6,0 mil private health expenditure.



SOURCE: System of Health Accounts (SHA) 2019, ELSTAT, 2020, OECD Health Statistics, 2020, data processing IOBE* For 2019 is estimation. For the definitions of total and public funding on health expenditure, see Annex 7. Data are in current prices
The index of GDP cumulative change in total health expenditure showed an increase of 1.7% in Southern countries, while an increase of +17.0% was recorded in EU23 (a decrease of -33.7% in Greece during the same period). Similarly, a cumulative decline of -4.5% was recorded in public health expenditure in Southern countries, while an increase of +17.4% was noted for EU23 (-42.5% decrease in Greece during the same period).



Figure 20: Index of cumulative change on health expenditure (%) Greece-EU23-Southern countries

SOURCE: OECD Health Statistics, 2020, IOBE data processing Southern countries (Italy, Spain, Portugal). Percentage changes between 2010 and 2019 have been calculated in the Fixed –rate Price Data (\$ 2010 PPS, OECD).

In Greece, total health expenditure as a percentage of GDP accounted to 9.4% (2009) and decreased at 7.8% (2019), indicative of a faster reduction in health expenditure compared to GDP reduction during the same period.

Figure 21: Total health expenditure (% GDP) Greece-EU23-Southern countries



Total health expenditure (%GDP)

SOURCE: System of Health Accounts (SHA) 2019, ELSTAT, 2020, Eurostat, OECD Health Statistics, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Public health expenditure as a percentage of GDP in Greece amounted to 4.6% in 2019 compared to 6.4% in 2009. This evolution shaped the rate of public health expenditure in Greece below EU23 average (8.0%), while in Southern countries that implemented economic adjustment programs, the percentage was at 6.4% for 2019.



SOURCE: System of Health Accounts (SHA) 2019, ELSTAT., 2020, OECD Health Statistics, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Public health expenditure accounts for 59.2% of total funding for expenditure health in 2019, compared with 68.3% in 2009, remaining below the EU23 average and Southern countries.



Figure 23: Public health expenditure (% of total expenditure) Greece-EU23-Southern

SOURCE: OECD Health Statistics, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-23: (not available data for Bulgaria, Croatia, Cyprus, Romania and Malta)

Total health expenditure per capita in Greece amounted to €1,362 in 2019 compared to €2,014 in 2009, that is €1,081 less than the average of Southern countries. Public health expenditure per capita declined in Greece by -41.4% between 2009 and 2019 and amounted to €807 compared to an increase of +29.8% in EU23 and a slower increase in Southern countries of 3.9% during the same period.



Figure 24: Total per capita health expenditure Greece-EU23-Southern countries

SOURCE: OECD Health Statistics, 2020, data processing IOBE Southern countries (Italy, Spain, Portugal). EU23 due to unavailability of data for other countries

Over the period 2008-2013, the per capita health expenditure in Greece declined by -7.3%, the largest among OECD countries, with an increase of 0.4% in the period 2013-2019.

Figure 25: Average per capita health expenditure evolution, OECD counties, 2008-2013 and 2013-2019



SOURCE: OECD Health Statistics, 2020

Households' monthly health expenditure was contracted by -22.1% during 2009-2019, when it reached €104.6, which accounted for 7.1% of total household expenditure (6.5% in 2009), indicating households' reduced purchasing power and increased participation in health expenditure.



Figure 26: Health expenditure of households (\in) per month-Greece

SOURCE: ELSTAT 2020, data processing IOBE. Household Budget Survey, which is conducted annually by the ELSTAT, provides information for the composition of total household spending, according to various socioeconomic characteristics of each household

During the economic crisis period, there was a shift of household expenditure mainly towards pharmaceutical and hospital care. Specifically, from €104.6 monthly health expenditure per household, 34.2% refers to pharmaceuticals and 31.6% to hospital services, 12.5% to dental services and 12.3% to other medical services.



Dental services

Hospital services

Pharmaceutical products

---- Health

SOURCE: ELSTAT, 2020, data processing IOBE

3.2 PHARMACEUTICAL EXPENDITURE

Total expenditure for pharmaceuticals and other medical non-durable goods accounted for \leq 4.1 bil. in 2019, recording a decrease of -32.1% compared to 2009. Correspondingly, public expenditure for pharmaceuticals and other medical non-durable goods from \leq 4.8 bil. in 2009 amounted to 2.3 bil. in 2019, recording a further decline of 52.8%, while private expenditure for pharmaceuticals and other medical non-durable goods increased from \leq 1.3 bil. in 2009 to \leq 1.9 bil. 2019.





SOURCE: System of Health Accounts (SHA) 2019, ELSTAT, 2020, data processing IOBE. Expenditure for pharmaceuticals and other medical goods, as reported in the OECD and SHA, includes expenditure on final consumption by outpatients of prescription and non-prescription pharmaceuticals, on-patented and generics. Medical goods are also recorded in the same category (see Annex 7).

Similarly, a downward trend observed in public per capita expenditure for pharmaceuticals and other medical non-durable goods, from €430 in 2009 to €181 in 2018. Public per capita expenditure for pharmaceuticals and other medical non-durable goods in EU22 increased from €289 in 2009 to €318 in 2018 approximately €137 higher than Greece, while in Southern countries was €257.



SOURCE: OECD Health Statistics, 2020, Eurostat 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal).EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta)

More specifically, the higher public per capita expenditure in 2018 for pharmaceuticals and other medical non-durable goods was recorded in Germany, Ireland and Belgium, while Greece (€181) is below the average of EU22 (€318). On the contrary, private per capita expenditure for pharmaceuticals and other medical non-durable goods in Greece (€167) is higher than the average of EU22 (€129), ranking 9th among EU countries.

Figure 30: Public & private per capita expenditure for pharmaceuticals and other medical non-durable goods (2018)



SOURCE: OECD Health Statistics, 2020, Eurostat, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta).

Public expenditure for pharmaceuticals and other medical non-durable goods in Greece is estimated at 1.1% of GDP in 2018 compared to 2.0% in 2009, close to EU22 and Southern countries.



SOURCE: OECD Health Statistics, 2020, Eurostat, 2020, data processing IOBE. Southern countries (Italy, Spain, Portugal). EU-22: (data not available for Bulgaria, Croatia, Cyprus, Romania, Malta).

Public outpatient pharmaceutical expenditure amounted to €2.0 bil. in 2020 compared to €5.1 bil. in 2009, resulting in an overall decrease by -60.8%. Accordingly, there was a significant increase in the contribution of pharmaceutical industry through mandatory returns and discounts (clawback and rebates). Specifically, in 2020 industry's contribution was €1.304 bil.

Figure 32: Public Outpatient pharmaceutical expenditure and industry's contribution (excluding patients' contribution)



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

Total outpatient pharmaceutical expenditure (including estimated patients' contribution) amounted to $\sim \in 3.9$ bil. in 2020. However, the significant decline in public outpatient pharmaceutical expenditure by 31%, during 2012-2020, resulted in a 379% increase on industry's contribution and in a 54% of patients' over the same period.



SOURCE: EOPYY 2012-2020, State Budget 2014-2020, data processing IOBE-SFEE Patient participation: What the patient pays to the reimbursed market (i.e. 0%, 10%, 25%) and the burden resulting from the difference between Retail Price - Reimbursement Price.

Public hospital pharmaceutical expenditure was set at €605 mil. for 2020, decreased by -20.8% compared to 2015 (€764 mil.), before introducing closed budget. The reduction of public hospital pharmaceutical expenditure resulted in a shift towards industry (through clawback and rebates), estimated at €569 mil. for 2020.



SOURCE: EOPYY 2012-2020, ESY.net 2012-2015, data processing IOBE-SFEE. Note: Estimations for 2020 for industry's contribution. EOPYY (1A) include Aretaeio hospital

PATIENTS' CONTRIBUTION

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

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

Patient co-payment in reimbursed medicines is distinguished in:

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

Other private payments for a medicine contain:

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

Demand side: Health and pharmaceutical expenditure



Figure 35: Patient participation in the reimbursement market (2020)

SOURCE: State Budget, company notes, data from IDIKA, data processing SFEE. The data for 2020 of patient participation are estimations.





SOURCE: Data from IDIKA (Institutional Patient Participation), OTC and Negative list, SFEE calculations based on EOPYY and IQVIA data (MAT12/2020). The data for 2020 of patient participation are estimations.

4.1 SUPPLY CHAIN FOR PHARMACEUTICAL PRODUCTS IN GREECE

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



SOURCE: ELSTAT, EOPYY, PanHellenic Association of Pharmaceutical Wholesalers

With a pharmacy density of 96 pharmacies per 100.000 inhabitants, Greece comes first in 2019 among the EU27 average of 32 pharmacies per 100.000 inhabitants.



Figure 37: Number of pharmacies per 100.000 inhabitants EU27 (2019)

SOURCE: ABDA. German Pharmacies, Figures Data Facts 2020, ELSTAT., 2020 * Data for Greece come from the latest available ELSTAT. data.

In 2019, 10,324 pharmacies operated in Greece, out of which 3,681 pharmacies (35.7%) were in the Region of Attiki. The number of wholesalers decreased from 137 in 2018 to 130 in 2019.





SOURCE: ELSTAT, 2020





SOURCE: ABDA, German Pharmacies, Figures Data Facts 2020, ELSTAT, 2020.* Data for Greece come from the latest available ELSTAT.

EOPYY PHARMACIES

EOPYY initially operated 5 pharmacies in Attica region and 1 in Thessaloniki, supplying high-cost medicines without copayment and without the confirmation of the prescription by the relevant social security fund (except 2 month). Currently, 32 pharmacies of EOPYY are in operation. In other parts of the country, insured citizens can obtain high-cost medicines for the treatment of serious diseases (Law 3816/2010) from EOPYY's local health units, after placing an order.

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

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

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

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

4.2 RESEARCH AND DEVELOPMENT (R&D)

In Greece, 3,114 clinical studies (1,800 completed) were conducted from 2002 up to 2020 (all types and phases)



Figure 40: Total number of clinical trials, all phases and stages (2002-2020)

SOURCE: Clinical trials.gov, 2020

Research & Development expenditure in the pharmaceutical industry (€51 mil.) accounts for 5% of total R&D expenditure in Greece in 2017, share lower than 2015 (8%).





SOURCE: Eurostat, 2019, data processing IOBE



4.3 PRODUCTION

According to Prodcom database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece was estimated at €1.4 bil. in 2019, approximately 24.4% higher than in 2018, while in comparison to 2010 is 52.5% higher.



SOURCE: Eurostat 2020, PRODCOM Database, data processing IOBE. *Any changes based upon review of data from Eurostat

The industrial index of domestic pharmaceutical production, recorded a significant increase in 2018 and 2019, but also in the first two quarters of 2020 with an expansion of 16% and 18% respectively, while in the last quarter of 2020 increased by 19% resulting in the index at 192.4 points, ie 92.4% higher than 2015 which is the base year. The production index in the first nine months of 2020 is 13.9% higher than in 2019. In the EU27 the pharmaceutical industry shows a smaller intensity increase since 2015, due to the higher starting point, while in 2020 it is 5.1% higher than in 2019.



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

SOURCE: Eurostat, 2021, seasonally adjusted and adjusted data by working days, data processing IOBE

The turnover of pharmaceutical production also increased in 2020, by approximately 15.8% compared to 2019, against to an increase of 0.6% in the EU27. In combination with the lower increase of the production index, it is estimated that the prices increased.



SOURCE: Eurostat, 2021, seasonally adjusted and adjusted data by working days, data processing IOBE

The gross Value Added (GVA) of domestic pharmaceutical sector is estimated at €1.2 bil. in 2019, amounted with a share of 6.6% in total manufacturing sector



SOURCE: Eurostat, 2020, data processing IOBE*Any changes based upon review of data from Eurostat* C21: Manufacture of basic pharmaceutical products and pharmaceutical preparations include only the companies active in the production of medicines and pharmaceutical preparations. In C21

manufacturing companies are not included firms that belong to subsector 46.46 Wholesale of pharmaceutical products.

Strengthening co-operation between international and domestic factories is a key pillar of the country's pharmaceutical sector activity. Specifically, 28% of pharmaceuticals are produced in domestic factories and in certified production facilities with high-educated personnel, while with appropriate incentives, domestic production of international pharmaceutical products may increase.

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



SOURCE: IQVIA FY 2020, *Locally Manufactured products LMP abroad = Products of international companies manufactured / packaged in Greece * Factories: 28 Greek-owned factories and 1 foreign-owned factory

4.4 EMPLOYMENT

In Greece 23.3 thousand people were employed in production of pharmaceutical products and pharmaceutical preparations in 2020, demonstrating an increase of 9.8% compared to 2019.



SOURCE: Eurostat, Labour Force Survey, 2021, data processing IOBE * Data for sectors 21.1 Manufacture of basic pharmaceutical products and 21.2 Manufacture of pharmaceutical preparations are included, employees in the wholesale sector of the wider health sector are not included

At the same time, according to the International Standard Classification of Education (ISCED) for 2019, the educational background of people working in the pharmaceutical industry was high, with 57.1% of total employees in pharmaceutical production with university education compared to 36.7% in the manufacturing and 23.1%, in the total economy, indicating the high educational training of the employees in the pharmaceutical industry.



Figure 49: Number of employees with tertiary education in pharmaceutical production (%)

SOURCE: ELSTAT, 2020, Employees Tertiary Education of total employment International Standard Classification of Education (ISCED 2011), data processing IOBE

In 2019, employment in the pharmaceutical sector represents 0.4% of total employment of the Greek economy, while this share increases to 4.6% with regards to employment in the manufacturing overall. The share of manufacturing is higher than the respective average in EU27 (2.2%).





SOURCE: Eurostat. Labour Force Survey 2020, data processing IOBE.



An important measurement for employed people is the recording time in Full Time Equivalent (FTE), by calculating total employment assuming that all workers are employed full-time. According to the available data, pharmaceutical industry recorded an increase of employment in FTEs by +28.9% during 2010-2019 compared to stagnation to total manufacturing, indicating that employment in pharmaceutical sector shows inflexibility.

Simultaneously, total wage cost increased by +36.1% compared to minor decline in manufacturing. The higher increase in wage costs compared to the increase in employment is an indication that the pharmaceutical industry is integrating highly paid employees, a feature which is also associated with the high educational background, full time and other characteristics of employees in the industry. The average hourly wage in the sector is almost double (\in 15.1) compared to manufacturing (\in 7.6) and almost triple compared to total economy (\in 5.7).

	Employment % change (FTE)	Compensation of employees	Average hourly wage (2019)
Total Economy	1.8%	1.8%	5.7€
Manufacturing	0.0%	-2.0%	7.6€
Pharmaceutical production	28.9%	36.1%	15.1€

Table 4: Change in employment and wages 2012-2019

SOURCE: Eurostat, National Accounts, 2020, data processing IOBE

4.5 SALES

Sales of pharmaceutical products to pharmacies & wholesalers (in values) amounted to \notin 4.4 bil. in 2019, showing an increase of +6.8% compared to 2018. Similarly, sales to hospitals & EOPYY pharmacies amounted to \notin 2.3 bil. in 2019 presenting a higher increase of +9.4% compared to previous year. Approximately, 65.7% of total sales supplied to wholesalers and private pharmacies, while the remaining 34.3% to hospitals and EOPYY pharmacies.



Figure 51: Sales of pharmaceutical products in values (bil. €)-Greece

SOURCE: EOF, 2020 (Pharmacies/Wholesalers at retail prices and Hospitals at hospital prices) Total pharmaceutical sales recorded monthly by the National Organization of Medicines (EOF) and include pharmaceutical sales by pharmaceutical companies to hospitals (at hospital prices) and Wholesalers / Pharmacies (at retail prices). Sales also recorded in terms of number of packages. Parallel exports in 2019 were €338 mil. and are included here

Regarding the number of packages, an increase of +1.0% was recorded in 2019 compared to 2018 (573.3 mil. packages) with an increase of 1.6% in pharmacies/wholesalers and an increase of 1.8% in hospitals/EOPYY pharmacies was depicted.



Pharmaceutical products can be classified according to their patent protection status. According to IQVIA (Q4 2020), the penetration rate of patent protected medicinal products (on patent) in terms of volume account for 8.3% of the market, which is higher than the average of EU18 (6.4%) which can be partly justified by their significantly lower prices in Greece compared to EU18 countries (€0.89 per unit on average compared to €1.84)
Respectively, the market share of non-protected pharmaceutical products amounted to 68.9% (off- patent 33.8% & generics 35.1%). It is worth noting that the penetration rate of off-patent is higher than the average of EU18 (19.7%), while penetration rate of generics is much lower than the average of EU18 (62.4%).



SOURCE: IQVIA, Q4/2020, Note1: only retail sales are included for all countries 2 The EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, Netherlands, UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary, Poland and Slovakia

According to IQVIA (Q4 2020), penetration rate in volume for off patent and generic products is partly justified by significantly lower prices for off patent products in Greece compared to the average of EU18 ($\in 0.27$ per unit compared to $\in 0.40$) and by slightly higher prices for generic products in Greece compared to the average of EU18 ($\in 0.18$ per unit compared to $\in 0.13$).



SOURCE: IQVIA, Q4/2020, Note1: only retail sales are included for all countries 2 The EU average is made up of available data from 18 countries: Greece, Ireland, Italy, Portugal, Spain, Belgium, France, Germany, Netherlands, UK, Finland, Norway, Sweden, Austria, Czech Republic, Hungary, Poland and Slovakia

Supply side: Pharmaceutical _____Industry and Economy



Figure 55: Share of generics -Greece value-volume (2012-2019)

SOURCE: OECD, Health Statistics 2020

The market of OTC in value followed an upward trend from €165 mil. in 2017 to €285 mil. in 2020, with an increase of 72.7% after its revision and implementation of Indicative Retail Price of Law 4472/2017 (Government Gazette 74 / A / 19.05.2017).



The general Distribution Medicines (GEDIFA), a subset of OTC (216 of the total 1,582 OTC), are available outside pharmacies and concern analgesics, antipyretics, antipyruitic, topical medications, laxatives (to treat constipation) and mouthwashes. Of the self-medication products, analgesics, cough and cold products, digestive products, dermatological products and vitamins recorded the largest sales.

Table 5:	Sales	self-medication	products	(mil.	€)
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Category	2013	2014	2015	2016	2017	%17/16
Analgesics	60	65	64	65	71	9.2%
Cough & Cold	67	69	66	65	75	13.9%
Digestives & Intestinal	23	24	25	28	32	12.7%
Skin Treatment	33	32	32	32	30	-5.1%
Vitamins & Minerals	62	70	68	67	72	7.2%
Rest categories	81	64	24	83	89	7.7%
Total	323	340	335	339	368	8.4%

SOURCE: AESGP,2018 *Note: Depending on the source of information used there may be deviations over EFEX-AESGP data

4.6 EXTERNAL TRADE

Imports of pharmaceutical products amounted to \notin 4.7 bil. increased by 33.1%, and exports amounted to \notin 2.9 bil. in 2020, increased by 48.3%, resulting on a deficit, of \notin 1.8 bil. Exports of pharmaceuticals show an increasing trend after 2016, however the increase in 2020 (+ \notin 947 mil) is double in value compared to the increase recorded in 2019 (+ \notin 447 mil).



Figure 57: Evolution of pharmaceutical trade balance (mil.€)

SOURCE: Eurostat International trade. EU Trade Since 1988 By CN8, 2021, data processing IOBE

The exports of pharmaceutical products in relation to the total Greek exports, correspond to 9.4% in 2020, due to their significant increase, compared to 5.8% in 2019, their share almost doubled. Respectively, imports account for 9.6% of total imports of the country in 2020, compared to 6.3% in 2019.



SOURCE: Eurostat International trade. EU Trade Since 1988 By CN8, 2021, data processing IOBE

The pandemic in 2020 changed the shares in pharmaceutical exports per country, as in some countries there was a 3-digit or even 4-digit increase in exports in the first ten months of 2020. France is for 2020 the first destination country for Greek pharmaceutical exports, with a share of 32.2 %, as it recorded an increase of 131.3% compared to 2019, followed by Germany with a share of 10.0% and a decline of 3.4%. The largest percentage increase in exports is observed in Japan, with an increase of 4,062.6%, now accounting for 8.0% of total pharmaceutical exports to Greece. In the first 10 countries, exports decreased, except for Germany and in Italy by 5.7% In terms of imports, Ireland is in first place with a share of 32.7%, followed by Germany, with a share of 20.0% and Belgium with a share of 8.7% and an impressive increase of 32.4% compared to 2019.

Country	Exports	Share	% change (2020 vs 2019)
France	935,058,006	32.2%	131.3%
Germany	290,367,184	10.0%	-3.4%
Japan	233,765,953	8.0%	4,062.6%
United Kingdom	190,416,022	6.6%	4.5%
Spain	125,038,339	4.3%	31.3%
Cyprus	123,306,860	4.2%	5.7%
Austria	120,880,195	4.2%	33.9%
Italy	95,457,671	3.3%	-5.7%
South Korea	79,621,692	2.7%	25.2%
Netherlands	77,292,358	2.7%	30.2%

Table 6: Exports of medicines by country (2020)

SOURCE: Eurostat, International trade, EU Trade Since 1988 By CN8, 2021, data processing IOBE

Part of the exports are parallel exports, which are recorded by EOF (National Organization for Medicines) based on sales declared by pharmaceutical companies.



SOURCE: EOF, 2020

4.7 PRICING OF PHARMACEUTICALS

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

Table 7: Pricing system

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

PRICE DEFINITIONS

Maximum Wholesaler Price: price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the wholesaler, which is calculated as a percentage on the maximum ex-factory price (Table 6).

Maximum Retail Price: price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy as set out in the respective ministerial decree and the applicable Value Added Tax (VAT 6.0%). In particular: a) 35% on the wholesale price for prescription non-reimbursed medicinal products b) for reimbursed prescription products see Table 6 and for non-prescription products up to 30% (Table 6)

Ex-factory price: price at which medicinal products are sold by the marketing authorization holders (MAHs) to wholesalers and is calculated based on the wholesaler price reduced a) for prescription reimbursed medicinal products by the Social Insurance Funds with price up to 200 \in by 4.67% and with a price exceeding \in 200,01 by 1,48% b) for prescription medicinal products which are not reimbursed by the Social Insurance Funds by 5.12%,

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

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

Table 8: Mark-up in the pharmaceutical supply chain						
	Reimbursed Products up to 200€	Reimbursed Products > 200.01€	Negative list products			
Wholesalers (over ex-factory)	4.9%	1.5%	5.4%			
Pharmacies	(Table 9)	(Table 9)	35%			
SOURCE: M.D. (4274/22.11.2019)						

Table 9: Percentage of profit (mark-up) pharmacies

Wholesale price (€)	Percentage	Wholesale price (€)	Percentage
	mark-up pharmacies		mark-up pharmacies
0 - 50,00	30.00%	900,01 - 1000	5.50%
50,01 - 100	20.00%	1000,01 - 1250	5.00%
100,01 - 150	16.00%	1250,01 - 1500	4.25%
150,01 - 200	14.00%	1500,01 - 1750	3.75%
200,01 - 300	12.00%	1750,01 - 2000	3.25%
300,01 - 400	10.00%	2000,01 - 2250	3.00%
400,01 - 500	9.00%	2250,01 - 2500	2.75%
500,01 - 600	8.00%	2500,01 - 2750	2.50%
600,01 - 700	7.00%	2750,01 - 3000	2.25%
700,01 - 800	6.50%	>3000	2.00%
800,01 - 900	6.00%		

Additionally, these mark-up margins mentioned above are applied to all reimbursed products sold in private pharmacies including products of L.3816/2010 list. When the latter are directly sold by private pharmacies and the respective cost is not reimbursed by EOPYY or any other SSF, pharmacist margin is set based on the table above.

Between 2002 and 2008, prices increased by 5.1% presenting the lowest increase between health index (+26.8%) and between categories of goods (22.3%), while from 2009 to 2019 the pharmaceutical price index decline with greater intensity (11.2% reduction).



SOURCE: Eurostat, 2021, Harmonised Indices of Consumer Prices (HICP), data processing IOBE)

4.8 HEALTH TECHNOLOGY ASSESSMENT (HTA)

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

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

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

STATE'S OUTSTANDING DEBTS TOWARDS PHARMACEUTICAL COMPANIES

The Hellenic Association of Pharmaceutical Companies (SFEE) collects and records data related to State's outstanding debts of its member companies (on a voluntary basis). Below an overview of total receipts, sales invoices and debts until 31.12.2020 only for the pharmaceutical industry are presented.

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

Specifically, findings show that:

The amount of government outstanding debts to SFEE member companies until 31.12.2020 amounted to € 686.8 mil., €353.3 mil. concerns EOPYY and €302.1 mil. concerns ESY while respectively until December 2019 amounted to 590.5 mil., €330.6 mil. concerns EOPYY and €259.9 mil concerns ESY of which 32% concerns EOPYY. Increase €96.3 mil. or +16.3% caused mainly from ESY hospitals.

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

State's outstanding debts towards _____ pharmaceutical companies



Figure 61: State debts evolution towards SfEE member companies' until per year (€ mil.)

SOURCE: SFEE

6.1 SYSTEM OF HEALTH ACCOUNTS (SHA)

In 2012, the Hellenic Statistical Authority (ELSTAT.) in collaboration with the Center for Health Services Management and Evaluation of the Nursing Department of the University of Athens and Dr. Markus Schneider (BASYS, Germany) published for the first-time statistics on National Health Expenditures (both public and private) based on the System of Health Accounts (SHA) of the Organization for Economic Cooperation and Development (OECD). The Hellenic Statistical Authority (ELSTAT.) publishes every year statistical data for the Funding on Health Expenditures at national level based on the new System of Health Accounts manual SHA 2011 of the OECD, against SHA 1.0 that used for earlier data. Based on article 6 of the European Regulation (EU) 1338/2008 of the European parliament re matters of public health and the respective under voting Implementation Regulation and in cooperation from OECD & WHO the new compilation of SHA data was created. As such. ELSTAT was obliged to communicate SHA data to Eurostat and to International Organizations (OECD and World Health Organization) according to the new SHA 2011.

Transition table from SHA 1.0 to SHA 2011 codes				
System of Health Accounts SHA 1.0	Funding Sectors (HF)	System of Health Accounts SHA 2011		
HF.1.1	General Government (excl. Social Security Funds)	HF.1.1		
HF.1.2	Social Security Funds (SSFs)	HF.1.2		
HF.2.2	Private Voluntary Insurance Schemes	HF.2.1		
HF.2.3	Private Households Out-of -pocket Expenditures	HF.3.1		
HF.2.4	Non Profit Institutions Financing Schemes	HF.2.2		
HF.2.5	Corporation Financing Schemes	HF.2.3		
HF.3	Rest of the World	HF.4		
HF.0	n.e.c	HF.0		
System of Health Accounts SHA 1.0	Health care providers (HP)	System of Health Accounts SHA 2011		
HP.1	Hospitals (public and private)	HP.1		
HP.2	Residential. Long-term care facilities	HP.2		
HP.3.1-3.4, HP.3.6	Providers of ambulatory health care	HP.3		
HP.3.5, HP.3.9	Providers of ancillary services	HP.4		

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

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

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

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

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

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

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

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

• Care Services. Rehabilitation

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

Ancillary Health Care Services

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

Products Supply for Outpatient Patients

o HC.5 Retailers and other providers of medical goods (pharmaceuticals, vision glasses,

hearing aids, orthopedic belts and accessories)

• Other Medical Products. Healthcare Management etc.

• HC.6 Preventive Care Services & Public Health

- o HC.7 Healthcare Management & Social Security Funds
- HC.9 Non-specialized services by type

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

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

Inpatient curative care services HC.1.1

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

• Day cases of curative care HC.1.2

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

Outpatient curative care HC.1.3

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

Pharmaceutical and other medical non-durables HC.5.1

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

• Therapeutic appliances and other medical durables HC.5.2

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

6.2 PHARMACEUTICAL EXPENDITURE-SALES

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

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

More precisely, pharmaceutical sales are composed of:

- (a) Public pharmaceutical expenditure which is incurred by social insurance funds (partially returned to public funds, as VAT of 6% and mandatory discounts/ rebates/ clawback from pharmacists and pharmaceutical companies are included);
- (b) Hospital sales from pharmaceutical products (invoiced at hospital price = ex-factory price minus 8.74% - rebates);
- (c) Sales of pharmaceutical products that are re-exported (parallel exports);
- (d) Sales of pharmaceutical products to citizens at their own cost;
- (e) Patient's copayment, which does not burden social security funds.

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

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



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