Deloitte.

Towards a Sustainable Healthcare Policy in Greece: Unlocking Value Through Pharma

Athens, May 2020

Abbreviations

AI-Artificial Intelligence
AMKA-Social Security Number (Αριθμός Μητρώου Κοινωνικής Ασφάλισης)
BeNeLuxA-Initiative involving health services in Belgium, the Netherlands, Luxembourg, Austria and Ireland
BI-Business Intelligence
CAGR-Compound Annual Growth Rate
CD-Communicable Disease
CEPS-Economic Committee for Health Products
CoE-Center of Excellence
COPD-Chronic Obstructive Pulmonary Disease
CPRD-Clinical Practice Research Datalink
DDD-Defined Daily Dose
DNA- Deoxyribonucleic Acid
DRG-Diagnosis-Related Group
EC-European Commission
EHR-Electronic Health Record
EKAPY-National Central Authority of Health Procurements (Εθνική Κεντρική Αρχή Προμηθειών Υγείας)
ELSTAT-Hellenic Statistical Authority (Ελληνική Στατιστική Αρχή)
EMA-European Medicines Agency
EOF-Εθνικός Οργανισμός Φαρμάκων
EOPYY-National Health Insurance Body (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας)
EPR- Electronic Patient Records
EPS-Electronic Prescription System
EPY-Healthcare Procurement Committee (Επιτροπή Προμηθειών Υγείας)
ERP-External Reference Pricing
ESY-National Health System (Εθνικό Σύστημα Υγείας)
EU-European Union
EUR-Euro
FDA-Food and Drug Administration (US)
GDP-Gross Domestic Product
GP-General Practitioner
GR-Greece
GVA-Gross Value Added
HAS-Haute Autorité de Santé
HEPC-Hepatitis C
HTA-Health Technology Assessment
IDIKA- E-Government Center for Social Security (Ηλεκτρονική Διακυβέρνηση Κοινωνικής Ασφάλισης)
INN-International Nonproprietary Name
IP-Intellectual Property
LFSS- Social Security Financing Law (Loi de Financement de la Sécurité Sociale)
LoE-Loss of Exclusivity
MEA-Management Entry Agreements
MoH-Ministry of Health
MoU-Memorandum of Understanding
NCD-Noncommunicable Disease
NHS-National Health System
NICE-(France)
OECD-Organization for Economic Co-operation and Development
OoP-Out of Pocket
OTC-Over the counter product
PEF-Pan-Hellenic Union of the Pharmaceutical Industry
PMSI-Programme de médicalisation des systèmes d'information
PPRS-Pharmaceutical Price Regulation Scheme
P&R-Pricing & Reimbursement
ROA-Return on Assets
R&D-Research & Development
RWE-Real World Evidence
SFEE- Hellenic Association of Pharmaceutical Companies
SME-Subject Matter Expert
SNIIRAM- Système National d'Information InterRégimes de l'Assurance Maladie
SU-Single Units
TA-Therapeutic Area
UK-United Kingdom
UN-United Nations
US-United States
VAT-Value Added Tax
VBP-Value Based Pricing
VR-Virtual Reality
WHO-World Health Organization
3D-Three Dimensions

Contents

Foreword

Growing and ageing population, a tidal wave of chronic diseases, exponential advances in life-extending therapies and technological advancements are driving the growth in healthcare expenditure globally. In the effort to respond to these developments, the healthcare systems ought to be **effective and people-centered**, **resilient**, with an **increased focus on protection** and committed to **improve access**. The outbreak of the COVID-19 pandemic reinforces the imminent need for a **rational yet sustainable approach, policy & budget** in order to support these priorities.

From a pharmaceutical sector perspective, as the trends drive expenditure to higher levels globally, the challenge is to create the framework in order for the industry to be a **catalyst** for achieving the targeted policies. Focusing in Greece, a **bold action plan** is required in order for the pharmaceutical industry to **unlock value** and contribute towards a **sustainable health system**. The action plan will deliver a **holistic vision** for a sustainable and patient centered pharmaceutical policy by accelerating reforms already in place, acknowledging impediments and leveraging best practices. Especially in the context of the current period, fostering a **collaborative environment** for all the participants is a prerequisite, so as to ensure a resilient supply of the market, greater efficiency in leveraging digital tools and the ability to offer to the patients the appropriate treatments.

With multiple stakeholders involved in a complex ecosystem, achieving a **balance between Supply and Demand** in a sustainable model is a significant challenge globally – particularly so in Greece, considering the increased number of participants throughout the value chain (Doctors, Pharma Wholesalers, Pharmacies). The **local inefficiencies** have contributed on putting extreme pressure to the system and led to an increased spending, which peaked in 2009, with the public expenditure per capita in Greece exceeding the EU averages significantly. Soon after this peak, the pharmaceutical sector became a priority area in the effort of the **fiscal adjustment** under the various 'MoUs', with the voting and implementation of numerous reforms, aiming, primarily, to contain public spending.

A key result of the measures taken was achieving the pursued fiscal adjustment – mainly as an outcome of the **reduced contribution of the Public sector**, rather than of curbing demand. As such, a **significant decrease of healthcare spending**, as well as on **Pharmaceutical** in particular, was achieved in the subsequent years, pushing Greece closer to the relevant EU averages. Particularly on Pharmaceutical spending, the results were supported by the **payback mechanism**, introduced in 2012. While this mechanism was initially introduced as a temporary measure, it has been growing year over year.

In this context, Deloitte, alongside with EFPIA and SfEE, attempt to set out the main elements of a **future vision** for the country's Pharmaceutical Policy in a **forward-looking way**, with the aim for this to act as a tool for the creation of a **sustainable plan** between the Industry and the Government, supporting **value enhancement** throughout the health care value chain. This vision cannot be disconnected from the challenges posed by the COVID-19 crisis which seems to be the catalyst for tidal changes in the society, the economy and the health sector itself.

As such, the ***Vision*** for a Sustainable and Patient Centered Pharma Policy should be designed with a view on achieving specific outcomes through enabling a **successful implementation** of outlined policies and **removing the barriers** that have hindered success in previous years. It also represents the **long term ambition** for a pharmaceutical industrial strategy aligned with government priorities.

In order for the Vision outcomes to be achieved, key policies and tools should be organized under categories of **levers,** associated with a clear **execution framework**. A set of **specific and prioritized initiatives**, outlined as the main outcome of this effort, aim to create **a roadmap** for achieving the targeted vision. In terms of materializing this declaration of common commitment between the Industry and the Public Authorities, a practice followed already in many European countries is co-signing a coherent **medium term plan**, detailing the initiatives to be taken by the various stakeholders.

Focusing on the key message of this report, a Sustainable and Patient Centered Pharma Policy has the potential to **create value for all stakeholders involved in the health care value** chain: the State, the industry, physicians and, most importantly, patients.

Methodology

For the development of the White Paper, a number of resources were leveraged in order to gather information, analyze data, generate insights and gain feedback on inputs and outcomes.

Stakeholders Consultation

More than 30 meetings were conducted with conducted with a variety of stakeholders, including public bodies, pharmaceutical companies, academia and associations' representatives.

SteerCo Meetings

Steering Committee meetings took place, with the participation of EFPIA and SfEE representatives on a regular basis, to monitor progress and gain insights.

Desktop Research

Research and analysis was conducted on topics concerning healthcare and pharmaceutical policies in Greece and abroad.

International Experts

The extensive Deloitte network of Healthcare Experts was leveraged for advise on the topic, as well as for gathering best practices.

The Challenge of Growth

The Challenge of Growth: *Healthcare Overview*

Growing and ageing population, a tidal wave of chronic diseases, exponential advances in life-extending therapies and technological advancements are driving the growth in healthcare expenditure globally.

Growth Trends

Global healthcare spending is on the rise, shining a light on health systems' need to increase efficiency. Before the outbreak of the COVID-19 crisis, the compound annual growth rate for health care spending across 60 countries was predicted to increase 5.4 percent for the period 2018–2022, compared to the actual just 2.9 percent over 2013–2017. The overall share of Gross Domestic Product devoted to health was forecasted at 10.5 percent for 2019 (1). Given the increased needs of the global population due to COVID, this trend is expected to be further reinforced.

The key global trends driving this growth include on one hand the extension of life expectancy and active life. On the other hand the explosion of chronicity in diseases and the expenditures tied to the transformation of "fatal" diseases into "chronic" ones, are turning innovation into a significant driver of investment in healthcare on a global level.

Drivers of Growth

Ageing Populations

Innovation

Disease Trends

Ageing Populations

Demographic trends suggest that life expectancy is growing and at the same time, our population is ageing dramatically. Particularly for the developed countries, those trends can be attributed to advances in medical technologies and healthcare, falling infant mortality, vaccination programs and a healthier way of living (such as reduced smoking). Average life expectancy, on a global level, has increased from **66,5 years** in 2000 to **72 years** in 2016 (2), – interestingly, latest estimates indicate that gains in longevity have slowed recently in various countries, a trend which, if confirmed, increases the urgency of putting in place a sustainable healthcare system.

In Europe, it is estimated that, by 2030, **25%** of the European Union's population will be **aged 65** and over, up from 19% in 2018 (3).

Social services, across regions, are facing challenges as the elderly require more long-term care and as the demographic changes have increased the dependency ratio significantly (the number of non-active population divided by the number of working age people), expressing the increased pressure on the economy in order to support its non-productive population.

Rise of Chronicity

The fight against communicable diseases (CD's), like Hepatitis, is making notable gains through better sanitation, improved living conditions, and wider access to health care. Despite the significant progress achieved in containing CDs, the market context is changing fast as there are increasing demands from ageing populations living longer with chronic non-communicable diseases (NCD's).

NCD's —most prominently, cancer, heart diseases, and diabetes—accounted for **71%** of the 56.9 million deaths reported worldwide in 2016; that share increases to **over 80%** in the most developed markets. NCDs' rise in both developed and developing markets is fueled by urbanization, sedentary lifestyles, changing diets, and rising obesity levels (4).

Between **2018** and **2040** the incidence of **cancer** in Europe is predicted to increase by **23%** **(5)**

Between **2017** and **2045** the number of adults with **diabetes** in Europe is projected to increase by **16%** **(6)**

(1) Deloitte, 2019 Global Life Sciences Outlook (2) WHO (3) Eurostat (4) Deloitte, 2019 Global Healthcare Sciences Outlook (5) Globocan 2018, Estimated Cancer Incident (6) International Diabetes Federation, IDF Diabetes Atlas, 8th edition

Innovation

Healthcare innovation is directed towards the creation of value through better outcomes, greater convenience, access and simplicity with, at the same time less, cost, complexity, and time required by both patients and providers. Product and service innovations like 3D-printing, AI and VR applications, biosensors and trackers, convenient care and telehealth expand the frontier through new business models that can deliver care in ways previously not thought possible.

From the scope of the pharmaceutical industry, focus was historically given on developing drugs which target different stages of the disease pathway. Despite the fact that patient centricity has long been a guiding principle for pharmaceutical companies, the strategy was mainly product-centered. Innovation is changing this, with new trends, such as Outcomes (or Value) Based Care, Precision Medicine and Digital technology, shaping the industry. Technological advancements in fields like genotyping and DNA sequencing have enabled the development of more advanced treatments, while significant focus has been given on developing orphan drugs in order to improve patient outcomes and treat rare diseases.

Between **2007** & **2017:**

- the EMA has given **1,544** orphan drug designations
- the FDA has given **2,711** orphan drug designations (1)

Worldwide is estimated that orphan drug sales will total **$217 billion** by 2023 up from **$118 billion in 2017** (1).

In this context, manufacturers are looking to move to a range of value added products under the moniker ***"beyond the pill"***. These innovative products may support the elimination of diseases (i.e. Global Strategy to eliminate hepatitis by 2030).

Combat the Challenge: Priority Areas

In the effort to respond to the developments which drive healthcare demand and expenditures, as well as to explore the performance of the Greek healthcare system, four priority areas are identified, as suggested by both the OECD and the European Commission (2).

(1) EvaluatePharma Orphan Drug report 2019, (2) OECD, Health at a Glance: Europe 2018

The Challenge of Growth: *Policy Priority Areas*

Effective and People-Centered Systems

Health systems' effectiveness can be expressed as their ability to produce positive health outcomes, aiming at improving the health of the population. **Effectiveness** is one of the most important elements of health systems' quality, together with **safety** and **patient experience**. All those elements, are contributing towards improving the overall performance of a health system.

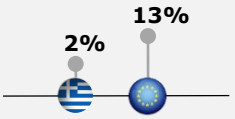
It is widely acknowledged that the healthcare sector's contribution to a healthy population has increased dramatically in the last fifty to sixty years. Health systems have made significant progress in treating life threatening diseases, like various types of cancers and heart attacks. Despite that, many disparities can still be identified between countries and also among genders, within each country. The improvements in the population's health can not be contributed solely to the health systems. Various factors, like technology and diet, are also contributing to that direction.

Moreover, health care systems need to **place people at the center**. This approach requires requesting more systematic feedback from patients, regarding whether they are better, or worse, following different health care interventions. Thus, leveraging data and measuring the effectiveness of health systems has become increasingly important.

Picker's Eight Principles of Patient Centered Care (1)

While notable steps forward have been taken in the last years, Greece appears to have significant improvement opportunities in terms of putting the patient in center:

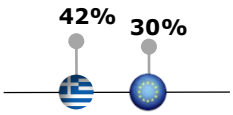
% of people who made a health appointment online
OECD 2018



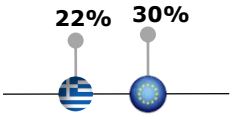
*In **Denmark**, the percentage of people who made a health appointment online, grew from **~28%** in 2012 to **~49%** in 2016 [EU28 leading performance]*

In 2016, Greece was the country with the highest proportion of health spending on inpatient care (including day care in hospitals), accounting for 42% of total spending and exceeding by 12% the EU28 of 30%. This phenomenon comes in contrast with most EU countries, where spending on outpatient care (including home-based curative and rehabilitative care and ancillary services) exceeds that on inpatient care, while the EU average for both inpatient and outpatient care is equal, at 30%. The proportion of health spending on long-term care in Greece, in 2016, accounted for 1.4% of total healthcare spending, significantly lower than the EU average of 13% (2).

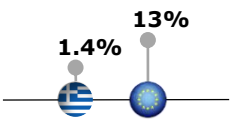
% of Health Expenditure for inpatient care
OECD 2018



% of Health Expenditure for outpatient care
OECD 2018



% of Health Expenditure for long-term care
OECD 2018



(1) Picker Institute and Harvard Medical School, (2) OECD, Health at a Glance: Europe 2018

Improved Access to Healthcare

Accessibility is one of the key priorities of policy action for healthcare systems. Emphasis on the importance of improving access to healthcare has been given from the United Nations, as Universal Health Coverage is one of the key Sustainable Development Goals.

Ensuring that parts of population are not excluded from receiving healthcare services is a result of interaction between different factors. Four most prominent can be identified:

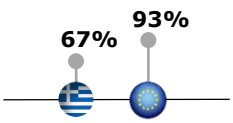
- **Breadth of Coverage**
- **Depth of Coverage**
- **Height of Coverage**
- **Availability of Care**

Law 4368/ 2016 was introduced in 2016 providing **universal health coverage** to all Greek citizens and also third-country nationals, holding a valid Social Security number (AMKA). As Greece is in the front line of the emerging refugee crisis, a large number of Social Security numbers have been issued to asylum claimants and refugees, during the past years. The breadth of coverage is not a complete indicator of affordability, as the range of services covered and the degree of cost-sharing applied to those services also matter.

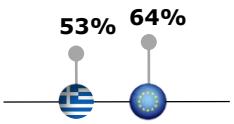
The **depth of coverage** highlights the proportions of costs covered for any type of service. Greece is among three countries, where the financial coverage for costs of inpatient care is below 70%, at 67%. Public coverage for pharmaceuticals is also below the EU average of 64%, at 53% (1).

Private spending on health in Greece is among the highest in the EU as **OoP** accounted for more than **one third of health expenditure**, in 2016.

% of public coverage for inpatient care
OECD 2018

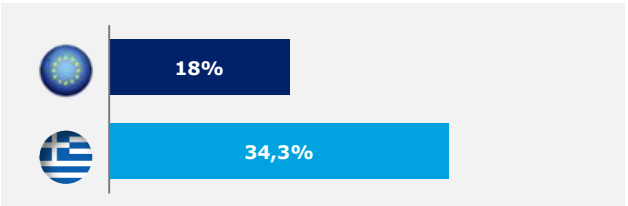


% of public coverage for pharmaceuticals
OECD 2018



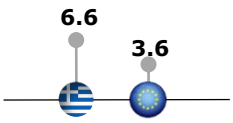
According to WHO, 3% of households in 2014 in Greece, fell into poverty as a result of OoP.

% of OoP on total healthcare spending
OECD 2018

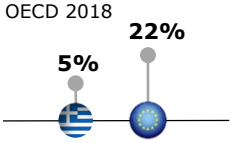


Access to healthcare is heavily dependent on the adequate staffing of the healthcare system - the number of doctors, its breakdown, their distribution across the country and the number of nurses. Greece has the **highest share of doctors** to population, but only 5% are GPs who act as gatekeepers (1). On the contrary, Greece has the **lowest share of nurses in the EU.** The geographical distribution of doctors, also highlights severe inequities, as physicians density varies from 2.9 to 8.6 per 1000 population (2).

Availability of doctors
(doctors per 1000 population)
OECD 2018

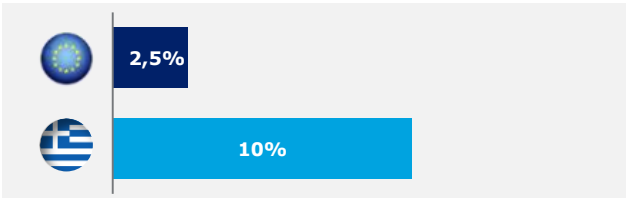


Availability of GPs
(share of general practitioners)
OECD 2018



The share of population reporting **unmet care needs** is generally low in most EU countries. In Greece, self-reported unmet need for medical care due to cost, distance or waiting times has trebled over the last decade and is now the **second highest in the EU**. There is enormous variability between the highest income quintile (3%) and the lowest (18.6%), highlighting **unequal access to services** experienced **across income groups** (1).

% of general population reporting unmet need for medical examination, OECD 2018



(1) OECD, Health at a Glance: Europe 2018 (2) ELSTAT 2016

Resilient Health Systems

Resilience refers to health systems' capacity to adapt effectively to changing environments, sudden crises and emerging needs, while remaining fiscally sustainable. In this context, significant focus is given to two pillars: reducing **wasteful spending** and leveraging **digital technologies**.

The importance of reducing wasteful spending, is resulting from the fact **that 20% of healthcare spending can be considered wasteful** (1) and could be reduced without hindering the overall performance of the system, as indicated from by data from various countries around EU.

Hospitals can be considered as the most integral but also expensive component of the healthcare system. The optimization of their operations can liberate resources to be used in different areas, without compromising quality of service.

In Europe, **20%** of healthcare spending can be considered as **wasteful**

One such area, is the reduction of avoidable admissions. A large number of hospital admissions could be averted through better prevention and management of both acute and chronic conditions outside the hospital.

There are 5 conditions for which hospitalization could be reduced and they are relevant in the European environment: 1) diabetes, 2) hypertension, 3) heart failure, 4) chronic obstructive pulmonary disease (COPD) and bronchiectasis and 5) asthma. These conditions accounted for **4.6 m. admissions**, across the EU, in 2015. When expressed as a percentage, of total **admissions that could be avoided**, this figure reached **5.6%** (1). **Data for Greece is not available, highlighting the fact that data and digital technologies are not leveraged, in order to move towards a more people-centered system**.

*In Europe, **5,6%** of hospital admissions due to five chronic conditions could have been potentially avoided.*

Reducing hospitalization requires a transformation and a long-term effort. Better primary and community care are needed in order to achieve better prevention and management of diseases outside the hospital.

***Portugal** established a call center that operates around the clock and, among other services, provides guidance to patients based on their needs. Among **800,000 callers in 2017**, 26% were advised on self-care, 42% referred to physicians and 24% directed to emergency services.*

The development of intermediate in-home care services has also emerged, in some countries, as an alternative to hospital-based care services.

*In some parts of the **UK**, since 2005 **"virtual wards"** have been set up to provide care at home for people recently discharged or at high risk of hospital admission. Evidence shows that they have **reduced unplanned hospital admissions** and the length of stay for the most at risk groups.*

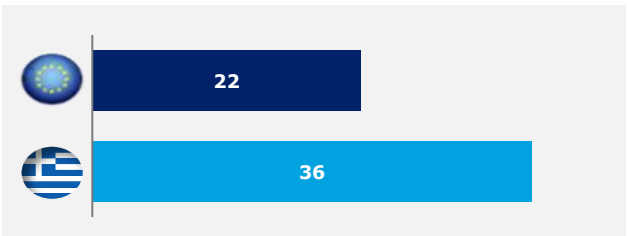
Curbing the overuse of hospital services can significantly contribute towards reducing wasteful spending.

(1) OECD, Health at a Glance: Europe 2018

The use of **Pharmaceuticals** is another area, where rationalization can lead to a more resilient health system, as medicines and medical goods represent around 1/5 of healthcare spending.

Encouraging rational use of pharmaceuticals is a key priority, as overprescribing and inappropriate use of medicines lead not only to increased spending but also extend the risk of therapeutic failure and the development of antimicrobial resistance. Both of those effects can be associated with higher costs for the system. In 2016, the EU weighted average consumption of antibiotics was 22 defined daily doses (DDD) per 1,000 population per day, while in Greece the consumption was more than 50% higher, at 36 DDD per 1,000 population per day (1).

Consumption of antibiotics,
In DDD per 1000 population per day, GR vs EU, OECD 2018



Improving adherence to prescribed medication is another priority area that can lead to reduced waste. The costs associated with **poor adherence** in Europe each year, are estimated to be approximately **€125 billion** (1), as a result of avoidable hospitalizations and emergency care visits.

*Modelled over a 10-year period in **five EU countries**, the potential **savings from increasing adherence** to antihypertensive treatment to 70%, have been estimated at **€332 m.** (2)*

Significant opportunities for improving adherence are laying ahead. Evidence has shown that, for specific chronic diseases, less than 1% of patients are adherent to treatment, one year after the diagnosis.

Apart from patient non-adherence, a range of other factors also contributes to wastage. Inappropriate repeat prescribing and dispensing processes, which may cause excessive volumes of medicines to be supplied, and also frequent self-medication are leading to increased waste (4).

*A study examining waste samples in Vienna, in 2015-16, found significant quantities of prescription medicines **discarded in household garbage**. By extrapolation, their value was estimated at approx. **6% of the national public pharmaceutical spending** in that year.*

Another approach to avoid wasteful spending for pharmaceuticals is to ensure that the medicines selected for procurement or reimbursement reflect good value for money. Value for money in the selection and coverage, procurement and pricing of pharmaceuticals can be ensured through Health Technology Assessment (HTA). If built with a holistic view on value, considering both societal and economic benefits, HTA can lead towards reducing waste without decreasing the expenditure, as better outcomes can be achieved through a better value for money relationship.

Digital technologies provide opportunities to deliver health services more efficiently. The use of ePrescription in Greece is a step towards reducing wasteful spending in the country, although it is not considered to be optimally leveraged and there are no reported data regarding its penetration.

The use of Electronic Medical Records (EMR) is not widespread in Greece. Efforts have been made to introduce EMR's, starting from the primary care physician offices. In fact, the penetration in primary care offices appears to be high (100% compared to the EU average of 81% (1)), but this should be mostly attributed to the small number of those offices. Indeed, in terms of specialist doctors, in both hospitals and private offices, the use od EMR's is estimated to be low.

(1) OECD, Health at a Glance: Europe 2018 (2) Mennini et al., 2015 (3) Vogler and de Rooij, 2018 (4) Trueman et al., 2010

Protection and Prevention

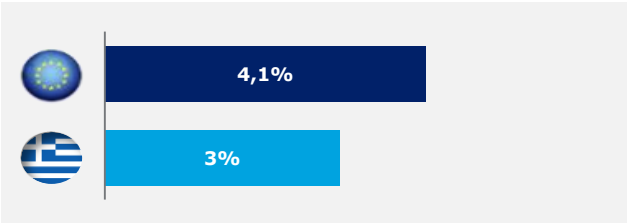
Protection and prevention are more and more important in today's environment as the number of people who die prematurely can be decreased through more effective disease prevention activities and targeted healthcare interventions. The current COVID-19 pandemic reinforces the focus to be given on vaccinations and adopting healthy lifestyles.

Effective vaccination coverage across all EU countries can be considered critical, in the effort to contain vaccine-preventable diseases. EU countries have established childhood vaccination programs, contributing to reducing many deaths related to these diseases, although the number and type of vaccines vary, to some extent, across countries. Greece has one of the highest rates in vaccinations for both measles and hepatitis B. More specifically, **97% of children were immunized against measles and 96% against hepatitis B**, compared with the EU average of 94.3% and 92.6% respectively (1). This trend however is expected to further grow, in the context of the COVID-19 crisis.

Efforts should also be put into preventing illnesses which are widespread and have a wide socioeconomic impact. One such example is the promotion of mental health. Mental health problems are associated with direct costs for treatment and also with lower employment and worker productivity. This is even more significant as more than one in six people across EU countries reported a mental health problem in 2016.

The total costs associated with mental health disorders, have been estimated to amount more than 4% of GDP across EU countries, equivalent to over €600 billion per year, making the promotion of mental health and the improvement of access to treatment for people with poor mental health, a priority. In Greece, the costs related to mental health are estimated to be 3% of GDP (1).

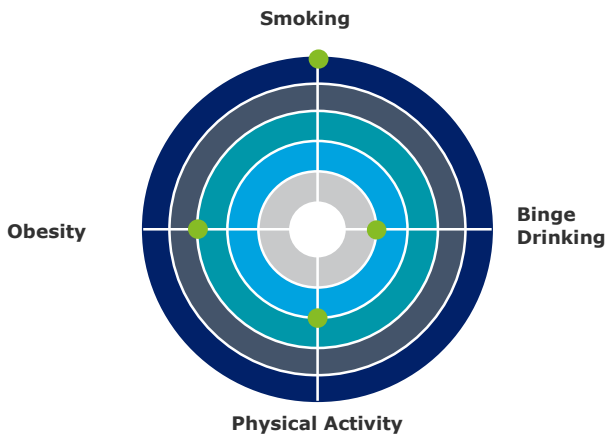
Costs related to mental health problems,
% of GDP, GR vs EU, OECD 2018



Smoking, alcohol, obesity and physical activity are the main factors that are associated with diseases and premature deaths, across EU. According to recent estimates 790,000 people in EU countries died prematurely in 2016, due to those factors.

Historically Greece has showcased relatively good population's health conditions, mostly due to factors such as healthy diet and lower alcohol consumption compared to other EU countries. Prevalent risk factors suggest that the main causes of diseases are rather behavioral, with smoking and obesity rates constituting major health issues. Greece has reportedly one of the highest smoking rates among EU28 countries (2), notably exceeding the European average. Overweight and obesity issues have been observed among all age groups, with **children and adolescent obesity being the second highest in Europe** in 2014 (3). In addition to these factors, the economic crisis has prompted a rise of poverty, unemployment and severe constraints of household budgets, which in turn have affected population's overall health behaviors and health status.

Public Health Issues in Greece
Note: *The closer the dot is to the center the better the country performs compared to other EU countries.*



These findings indicate the importance of focusing on health promotion and disease prevention. Actions in that direction could help reduce the burden of many diseases, relieve pressure from the system and avoid a large number of premature deaths.

(1) OECD, Health at a Glance: Europe 2018 (2) Eurostat (3) State of Health in the EU-Greece Country Health Profile 2017

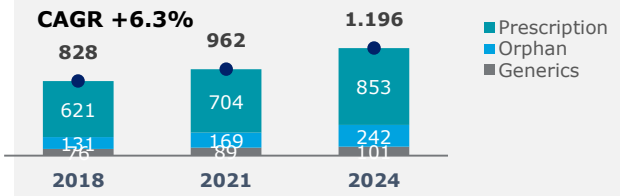
The Challenge of Growth: *Pharma Perspective*

As the global trends drive pharmaceutical expenditure to higher levels, the challenge is to create the framework in order for the industry to be a catalyst for achieving the targeted policies.

Growth in Pharma Expenditure

While differences between countries exist, innovation drives much of the growth in pharmaceutical expenditure worldwide, with novel, but costly, therapies that address key unmet needs as a focal point. Before considering the impact of COVID-19, global pharmaceutical spending was predicted to outpace overall health care spending, also raising the need for rationalization. Worldwide expenditure on prescription medicines was expected to rise from US$828 billion in 2018 to ~US$1.2 trillion by 2024. From 2018 to 2024, CAGR for was expected to be 6.3%, or six times the actual 1.2% over the period between 2011 and 2017 (1). While a negative impact on demand is expected due to delays of non urgent treatments, supply chain disruptions and delays in launching new drugs, this is expected to be neutralized by the increased demand for particular treatments (such as anti-virals), stockpiling effects and an increase in vaccinations. Overall, analysts expect only a marginal slowdown in the annual growth rate in the global pharmaceutical spending, if any.

Worldwide Expenditure on Prescription Drugs, 2018-2024 in b.$ - before COVID-19 effect



This growth however can provide the opportunity to the pharma sector to act as a **catalyst towards a sustainable healthcare system, via:**

1. Efficient Treatment of Chronic Diseases

The value of pharmaceutical innovation lies not only in the fact that new medicines improve the health and quality of life of patients, but also in their ability to improve the overall efficiency and sustainability of the healthcare system. Pharmaceutical innovation is assisting in tackling diseases more efficiently and improving the health status of the patients. The use of new medicines can offset healthcare costs via the decrease in hospitalizations, examinations and medical visits, and significantly contribute to cost-savings.

2. Adherence Reducing Hospitalizations

Significant outcomes and savings can be achieved when innovative therapies are combined with effective management of the patient throughout the treatment as patient adherence to treatment can be closely linked to health expenditure, especially in the context of the COVID-19 crisis. Research in the US has shown that an extra dollar invested in greater adherence can produce a saving from 10 dollars in health costs, for diseases linked to hypertension, to 4, for diseases linked to dyslipidemia (2). On the contrary, non-adherence leads to a series of incremental healthcare costs, in cases where diseases enter in acute phase.

3. Patient Centered Approaches

In an effort to reduce the time to treatment, improve access to medicines and enhance adherence, many companies are involved in the transformation of the health system shifting their focus from treatment to prevention and more notably to the total cost of illness, by providing scalable and efficient customer solutions within hospitals. These solutions accelerate patient journeys to care and, on the same time, aim to address the pain points of the ecosystem.

4. Social Responsibility

The pharmaceutical industry can also create societal value, having the potential to cover the needs of vulnerable social groups for medicines and essential medical goods. It can also promote education and awareness regarding rational use of medicines and healthy lifestyles and support the state in the development of infrastructure projects in the field of healthcare (e.g. creation of registries) through PPPs.

A Plan Towards the Future

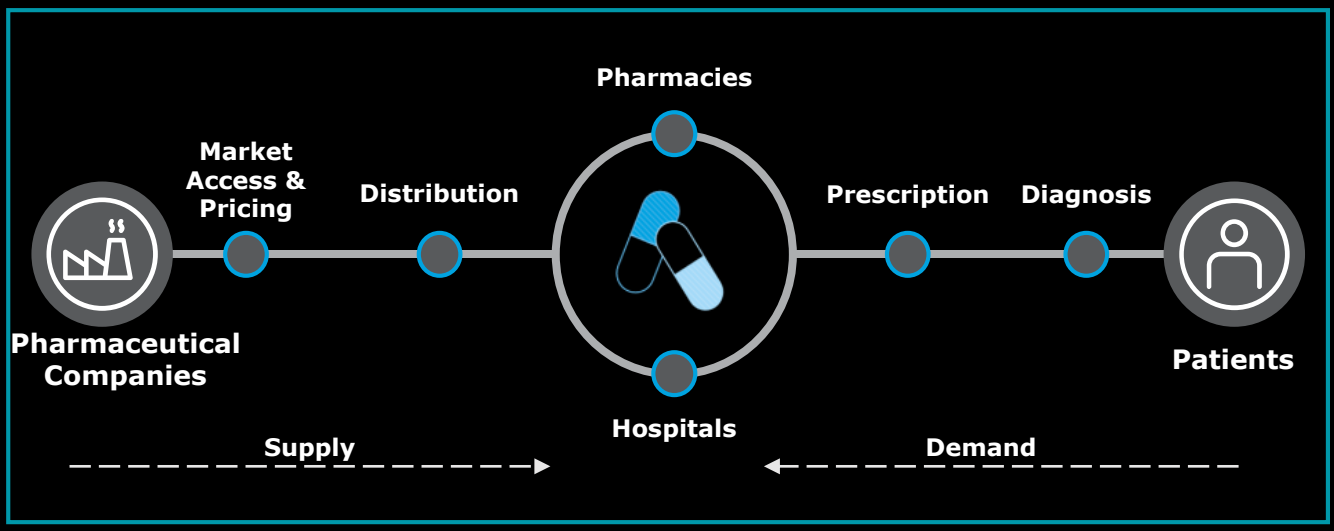
A **bold action plan**, which will enable the pharmaceutical industry to **unlock value** and contribute towards a sustainable health system, is required. The action plan will deliver a **holistic vision for a sustainable and patient centered pharma policy** by accelerating reforms already in place, acknowledging impediments and leveraging best practices, in a period where the healthcare budget is under unprecedented pressure and the collaboration of the stakeholders is a prerequisite.

(1) Deloitte, 2019 Global Life Sciences Outlook (2) Sokol M., McGuigan K., Verbrugge R., Epstein R., Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost, Medical Care. 2005 Jun;43(6):521-530

The Pharma Sector in the MoU Era

The Pharma Sector in the MoU Era: *Ecosystem*

With multiple stakeholders involved in the Greek Ecosystem (Doctors, Pharma Wholesalers, Pharmacies), achieving a balance between Supply and Demand, in a sustainable model, is a significant challenge.



Until recently, the Greek market was one of the few with no elaborate mechanism in place for the evaluation of cost-effectiveness and affordability of new medicines. Without filtering the number of medicines, the positive reimbursement list contains more than **7,000 medicines,** at least ten times more than any other EU member state (1).

With over 10 thousand pharmacies in operation, Greece has **96 pharmacies per 100 th. inhabitants** (vs. EU28 average of 31 in 2017), while the number of pharma wholesalers is equally high (128 in 2017) (2).

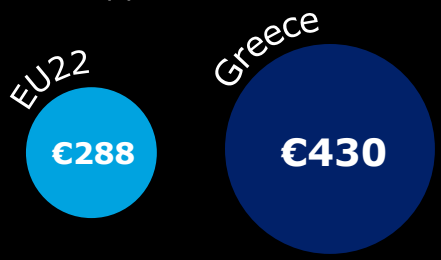
Despite the various reforms, the intermediate layers account in 2019 for **over 30%** of the Retail Price (3).

Furthermore, the Doctors constitute a critical group of stakeholders, with Greece presenting almost **two times as many doctors** as the EU average in 2016 (6.6 vs 3.6 per 10 th. inhabitants) (4). Still, according to the European Commission, the main problem is not a lack of doctors, but a lack of generalists, the uneven geographic distribution of doctors, and the lack of doctors in public facilities.

The primary health care sector has been historically underdeveloped in Greece – with a share of spending of **22% for Outpatient Care** vs. 30% in EU (4). The majority of public health centers, rural surgeries and private doctors' offices do not provide generalist or preventive care or act as gatekeepers, but rather provide specialized ambulatory (outpatient) services.

All those inefficiencies have contributed on putting extreme pressure to the system and led to an increased spending, which peaked in 2009 at 5.1B €, in the outpatient market, with the public expenditure per capita in Greece exceeding the EU averages by almost 60%.

Public Per Capita Expenditure on Pharma (€), Greece vs. EU22 (5), 2009

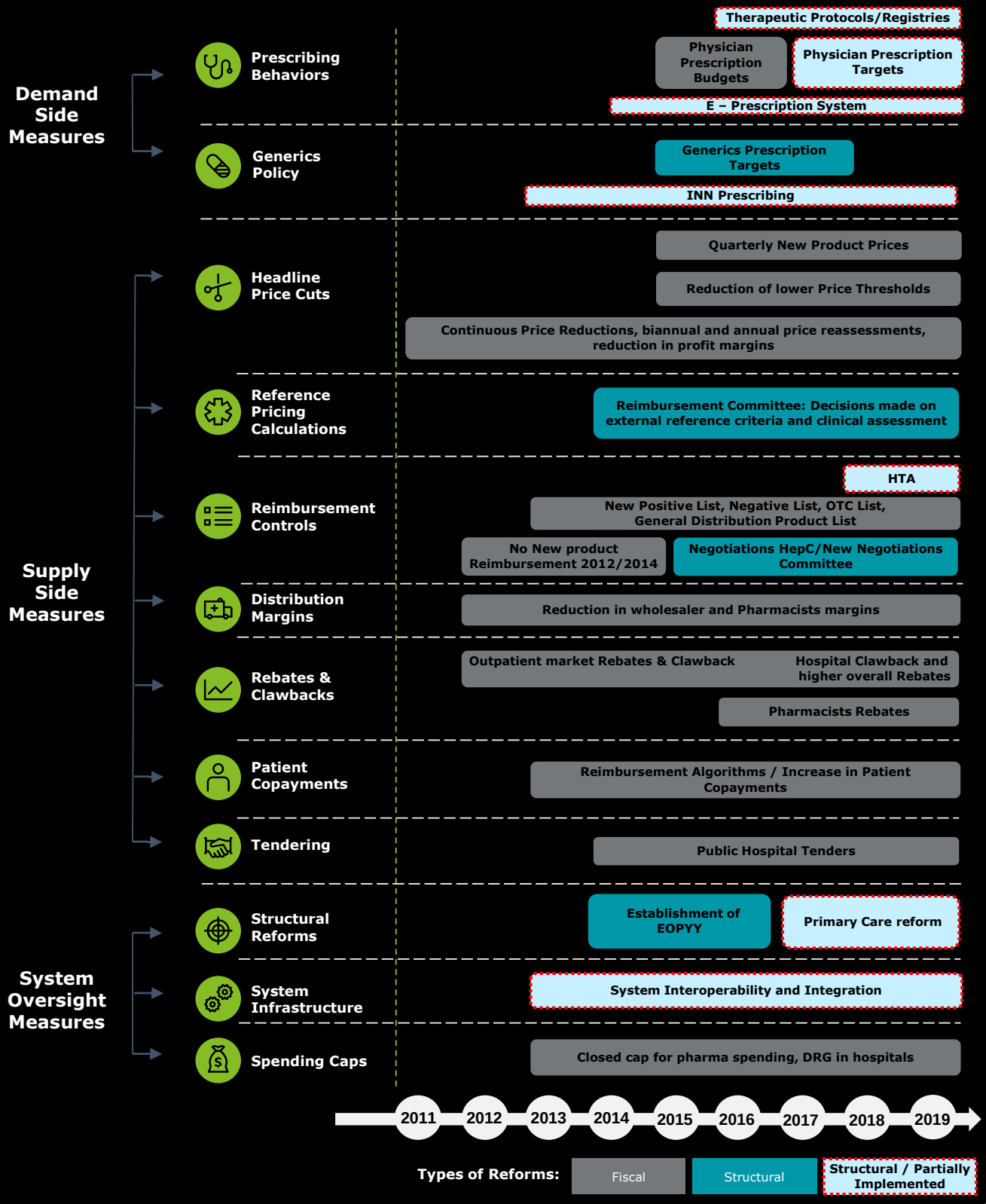


Soon after this peak, the pharmaceutical sector became a priority area in the effort of the fiscal adjustment under the various 'MoUs', with the voting and implementation of numerous reforms, aiming to contain public spending.

(1) Deloitte Analysis (2) IOVE-SFEE The Pharmaceutical Market in Greece Facts & Figures 2017 (3) IQVIA Market Trends Q1/2019 (4) OECD Health at a Glance: Europe 2018 (5) IOVE-SFEE The Pharmaceutical Market in Greece Facts & Figures 2015-2016

The Pharma Sector in the MoU Era: *Key Reforms*

In an attempt to contain the pharmaceutical expenditure, several reforms have been introduced in the last years - in part due to the country's commitments to the financial adjustment programs. Still today, distortions are apparent in the market, as several structural measures have only been partially implemented.



Source: Deloitte Research, "EFPIA SFEE Meeting" slides

Key Reforms: *Demand Side*

Prescribing Behaviors

An electronic prescription system (EPS) was introduced in 2012, with the aim to rationalize demand via monitoring the prescribing behavior and the dispensing patterns. While the EPS is widely implemented, no formal auditing of the prescribing behavior is carried out in order to ensure compliance.

Structural reforms in the form of therapeutic protocols and fiscal interventions as physician prescription budgets, were also introduced. In January 2014, a ceiling of 80% of the previous year's prescription budget was imposed on the monthly amount that a doctor could prescribe - this measure was amended in 2015 and the allowance would depend on the physician's specialty, the number of patients, the region and the season (1). In total, 72 therapeutic protocols have been published in MoH's website, but their implementation in practice remains to be evaluated (2). Patient registries have been developed only for specific diseases (hepatitis C, chronic myeloid leukemia and multiple sclerosis) and are not yet leveraged.

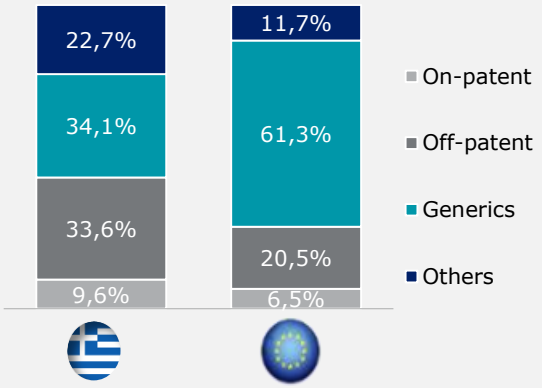
The prescription mechanics should be reviewed for the Hospitals as well, in order to ensure that the appropriate controls are in place and the protocols followed.

The coverage of the uninsured population is another factor that contributes to increased demand and adds an extra dimension to the efficient gatekeeping of EPS. Between 2018 and 2019, according to EOPYY, the numbers of uninsured people who obtained access not just to hospitalization but also to retail medicines increased by 45%.

Evidently, the volume of monthly prescriptions, despite all reforms undertaken, has increased **from 4.5M to 6.5M** between 2012 and 2016 (3).

Volume of Monthly Prescriptions (3)

Penetration of Medicines Based on their Patent Status, GR vs EU18, 2019 (4)



Generics Policy

Generics penetration in the Greek market has been lower to most EU member states. In 2019, the generics market share in Greece in volume terms was 34.1% on average in comparison with 61.3% of the EU18 average (4) - however in certain categories the penetration is significantly higher even compared to the EU average.

Following the establishment of the EPS in 2012, the use of generics has been promoted by a number of measures, including: requiring physicians to prescribe medicines using the active substance (allowing the use of brand names only in specific circumstances), requiring 50% of medicines prescribed in public hospitals to be generics and introducing mandatory generic substitution in pharmacies. Also, a policy is in place stipulating that the maximum price of generics cannot be set at more than 65% of branded drugs. Still, these initiatives have not met the initial targets, due to the distortion of the pricing mechanism, an established culture of preferring branded medicines instead of generics, an inconsistency in the existence of clinical guidelines (covering all incidents), as well as to technical setup of the market (for example, the prescriptions system is not "locked" for generics prescribing).

(1) European Observatory on Health Systems and Policies, Health Systems in Transition, Greece, vol 19 (2) Deloitte Analysis, (3) SEV, (4) IQVIA Market Trends Q1/2019

Key Reforms: *Supply Side*

Headline Price Cuts

Greece implemented a series of measures in order to rationalize the pricing mechanism, including the quarterly introduction of price list for new medicines and the bi-annual re-pricing. For the off-patent medicines the price would be either the average of the 3 lowest prices in the EU or 50% of the original price. For generic medicines, the price was fixed at 65% of the branded price prior to expiration. It was also determined that each repricing would have a maximum reduction of 10%.

These reforms caused frequent changes in the medicine price list, thus creating a volatile environment, as well as distortions. On-patent drugs are priced lower than other EU countries, generics are priced higher and off-patent drugs prices are close to the EU levels.

In an effort to enhance stability, the government proceeded to further reforms in 2019 aiming to further to improve the pricing mechanism. Specifically, Greece moved to a less frequent (annual) repricing of medicines, where ceilings of 0% for increase and 7% for decrease were agreed, in each repricing for on-patent and off-patent medicines.

Distribution Margins

In the complex Greek healthcare system, the matter of profit margins for all stakeholders has always been under discussion between the European Institutions and the Government.

As already stated, Greece has the highest number of pharmacies per capita (2), while the wholesalers operate at a regional rather than national level, as this part of the value chain is highly regulated.

Key issues concerning the regulated distribution chain in Greece go beyond the various layers of margins (which are currently close to the EU average) and include the limited opportunity for the pharma companies to control their stock and thus increase accountability (e.g. as a means to control parallel exports).

Reference Pricing Calculations

The majority of the European countries employ external reference pricing (ERP) as well as HTA. The pricing of reimbursed pharmaceuticals in Greece has traditionally been based on ERP, as Greece is a dynamic player of the European ERP system.

For many years in Greece, the first pricing for branded, biological, bio-similar, hybrid and biotech medicines, as well as their re-pricing was determined by the average of the 3 lowest EU Member States' prices.

This mechanism was amended with a new reform in 2019. This happened in an effort to restrict the basket to the same currency zone and avoid distortions due to currency fluctuation. Under the new mechanism, the prices for the on-patent and off-patent medicines would be determined by the average of the two lowest ex-factory prices among the EU-zone member states.

Until today, no action has been taken regarding a move towards Value Based Pricing.

Reimbursement Controls

Greece established the necessary framework for Health Technology Assessment (HTA) and the negotiation committee in January 2018, in an attempt to redesign the reimbursement process and introduce positive and negative reimbursement lists.

The current legislation suggests that in scope are new active substances, new indications of already reimbursed drugs, new drug combinations, new generics, drugs appearing in the positive list during the last 3 years, and all therapeutic analogues for which an application for inclusion has been filed (1).

Key concerns for the first months of operations include the volume of drugs in the positive lists (much higher compared to other EU countries - with 7,000 medicines compared to less than 1,000 across Europe, as estimated by the market), as well as the staffing of the Committee with full time professionals and the governance procedures (e.g. the role of EOPYY, the role of the Ministry and the role of the Patients).

(1) Implementing HTA in Greece, P. Kanavos V. Tzouma A.M. Fontrier K. Souliotis, (2) IOVE, The Pharmaceutical Market in Greece 2018

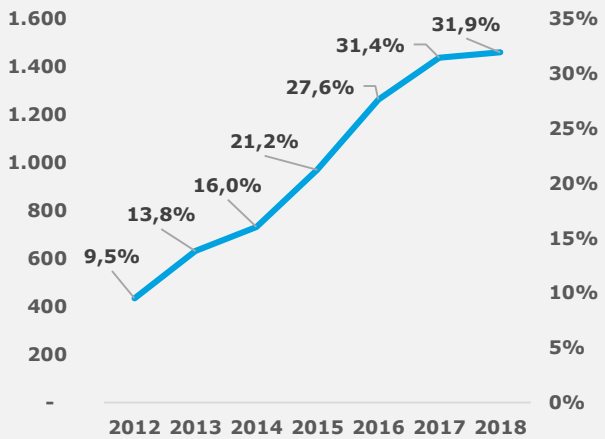
Rebates & Clawback

The Clawback is the amount that pharmaceutical companies have to return to the state when spending for pharmaceuticals exceeds the public budget.

In 2012, a Clawback mechanism was imposed on pharmacies and pharmaceutical companies for the out-patient market. In 2016, a similar mechanism was also introduced for the in-patient market as well. The implementation of the Clawback mechanism followed the Rebates introduction in 2009. currently, 90% of the Clawback that companies have to pay depends on market share and 10% on the market penetration level of each medicine. A proposal was made by the MoH, on December 2019, to move to a 75% - 25% split and to exclude the generics and the off-patent medicines from the 25% market penetration growth.

Although Clawback was introduced as an emergency measure to ensure patients' access to medicines, it is expected to apply at least by 2022, while it has been growing year over year. Indicatively, in 2018, total industry contributions reached ~32% of total public pharmaceutical spending for outpatient medicines, compared to 10% in 2013 (1).

Total rebates & clawback (€ '000 & as a % of total outpatient public pharma spent) (1)



Patient Copayments

Following the reduction in the contribution of the Public Sector, the market experienced a significant surge in patient contributions through increased copayments.

In spite the fact that the size of copayments is in line with the EU average, the structural inefficiencies of the Greek healthcare system, lead to higher than the EU average OoP payments for retail pharmaceutical by the patients. More specifically, OoP in 2016 constituted about 47% of the expenditure on retail pharmaceuticals, in comparison with the EU average of 34% (2).

Co-payments in Greece apply at a rate of 0% for life-threatening diseases, 10% for chronic diseases and 25% for all other types of disease.

Hospital Tendering

In the effort to contain healthcare spending and address the absence of an ePrescription system in hospitals, a number of tools were adopted between 2010 and 2014, such as effective procurement policies, e-auctions tendering and negotiation of contracts with suppliers as well as the establishment of a Pricing Observatory for Medical Supplies in 2009.

Although Greece met the targets, with approximately 38% savings in medical products (3), the responsible organization (Healthcare Procurement Committee - EPY) was abolished. A few years later, the authorities set up a new body responsible for central procurement (EKAPY), with the goal of achieving a share of centralized procurement in total hospital expenditure of 30% by mid-2020 and 40% by mid-2022 (4).

However, it is not yet possible to assess whether EKAPY will improve the results achieved with EPY, due to the rather long period in which activities were interrupted, to the fact that EKAPY has not yet launched genuinely new tenders and to concerns regarding the staffing the new organization.

(1) SfEE (2) OECD, Health at a Glance: Europe 2018 (3) SEV - Thematic Study on Public Procurement System Reform, 2015 (3) EC, Enhanced Surveillance Report 2019

Key Reforms: *System Oversight*

Structural Reforms

In 2011 all public health insurance funds merged into EOPYY, a unified health fund. This proved to be a major development in health insurance with the aim to equalize contribution rates and health care benefits across occupational groups, for those employed and their dependents. EOPYY acts as a single purchaser of health services and pharmaceuticals for the insured population. While the implementation of EOPYY has been an improvement so far, some challenges remain, notably the effective allocation of assets to EOPYY, the persistence of arrears in their payments to public and private providers and the collection of contributions.

In 2017, with the primary care reform the role of GP was introduced and local healthcare units were developed. However, the primary care remains weak with reforms not fully implemented yet. Another important regulation was the effort to achieve a greater decentralization of health care authorities - 13 regions were created and were expected to play a much greater role in managing and organizing human resources in the ESY and the provision of primary health services.

Furthermore, since 2016, the access of uninsured people was voted, a measure which aimed to cover the increased number of unemployed population in the country.

System Infrastructure

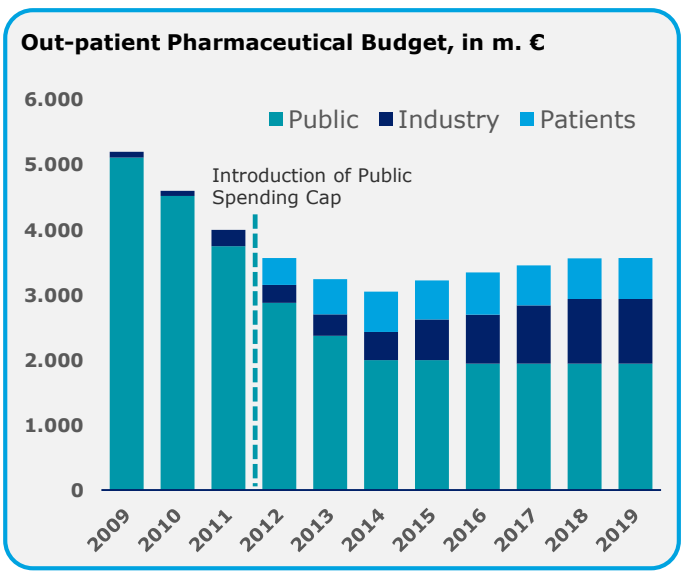
Significant progress has been made in creating the appropriate infrastructure in public hospitals as well as in EOPYY and the Ministry of Health. EPS has been established and is run by IDIKA. EOPYY has developed a BI system which collects and processes all the data of prescribing. All major hospital have their own BIs, which have been developed by different providers. All data from the hospitals BI systems are gathered by MoH's BI system.

The main challenge in the digitization of the health sector arises from the lack of integration and interoperability between the systems that have been established or are in the process of being established. The integration could facilitate the data exchange and sharing.

Digital tools can help improving monitoring and control of prescription and consumption of services and goods and will render a future referral system and care coordination more effective, reducing the use of unnecessary pharmaceutical, specialist and hospital emergency care.

Spending Caps

Expenditure ceilings in the public pharmaceutical budget were introduced, in both the out-patient and the in-patient market, as a safety net to ensure the fiscal stability of the system. Since 2016, Public outpatient pharmaceutical budget was set at € 1,945 billion annually and has remained stable onwards, marking a decrease of ~62% from 2009. Public hospital budget was set at € 510 million, noting a decrease of ~33% from 2012. The public hospital budget was further decreased to € 455 million in 2018. In 2018, the inpatient budget was raised by € 50 million for the first time since the introduction of closed budgets, in an effort to cover the emerging patients' needs (1). However, such measures are not considered as forward looking. They aim at solving short term problems and do not provide the required fiscal space.



(1) IOVE, The Pharmaceutical Market in Greece 2018

Current State: The Impact of the Reforms

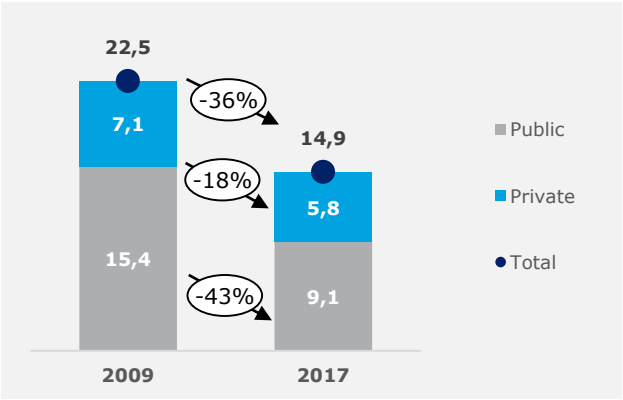
Current State: *Expenditure on Healthcare*

The adopted reforms led to a significant decrease in healthcare spending, aiming to meet fiscal targets. The adjustment, however, was achieved via an abrupt reduction in the public contribution, pushing Greece below the relevant EU averages.

Healthcare expenditure in Greece

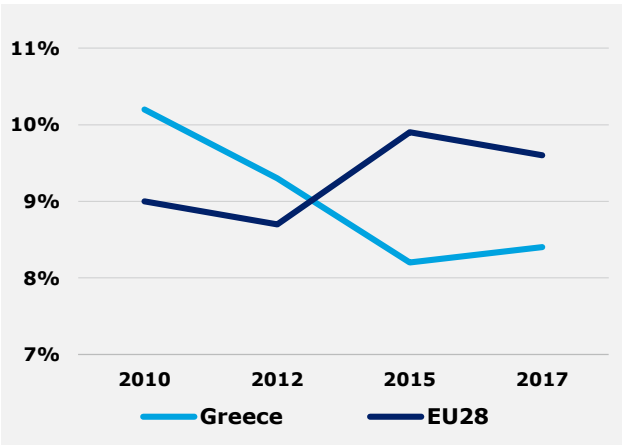
Healthcare expenditure in Greece has been decreased by 34% between 2009 and 2017. In 2017, total healthcare spending was 14.5B€, with the public spend expenditure reaching 8.8B€ and private expenditure reaching 5.6B€. Although since 2009, public health expenditure in Greece has decreased by ~43%, total health expenditure has decreased at a lower rate by around 36% (1).

Healthcare Expenditure (b.€) , Greece, *IOVE 2017*



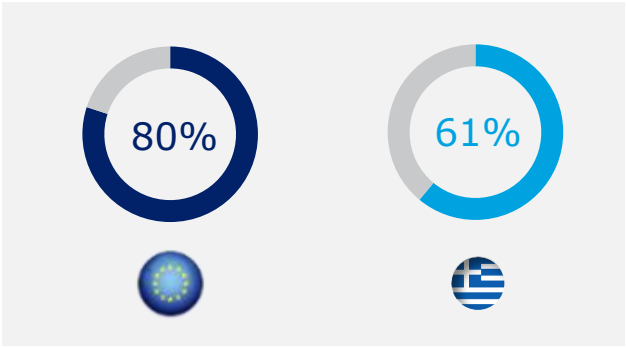
Health expenditure, when expressed as a percentage of Gross Domestic Product (GDP), has decreased from 10,2% in 2010 to 8,4% in 2017, lagging behind the EU average of 9,6% (1). This reduction combined with the financial crisis and high-unemployment rates contributed to worsening health outcomes and inadequate access to health services.

Health expenditure as share of GDP, IOVE *2010 - 2017*



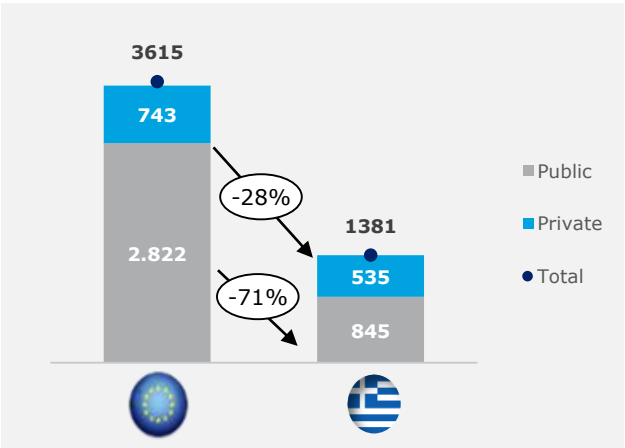
The fiscal adjustment measures, led to a decrease in the public spending which was partially covered by a respective increase of private payments. The share of Public Funding on total healthcare expenditure reached 61%, in 2017, below the EU average of 80% (1).

Share of Public Funding in total Healthcare Expenditure, *IOVE 2017*



This gap becomes even more evident when viewed from the perspective of per capita expenditure (€1,381 in Greece compared to the EU average of €3,615), highlighting the underfunding of the healthcare sector which has put increased pressure to the population via 'Out of Pocket' payments (1).

Per Capita Health Expenditure (€), GR vs EU, IOVE *2017*



(1) IOVE – The Pharmaceutical Market in Greece 2018 (2) SfEE

Current State: *Expenditure on Pharmaceuticals*

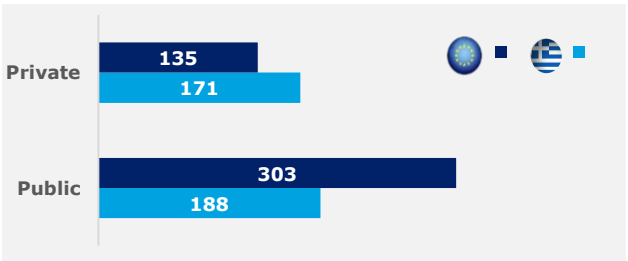
Similarly, the expenditure for Pharmaceuticals dropped sharply between 2009 and 2017, from €6.1 to €4 b. A key result of the measures taken was achieving the pursued fiscal adjustment through the reduced contribution of the Public sector, rather than of curbing demand.

Pharma Spending in Greece

In an attempt to meet the targets set by the MoUs, public expenditure for pharmaceuticals and other medical non-durable goods in Greece, as a share of GDP, was decreased by 2017 to 1.1%, coming closer to the EU22 average of 1%(1).

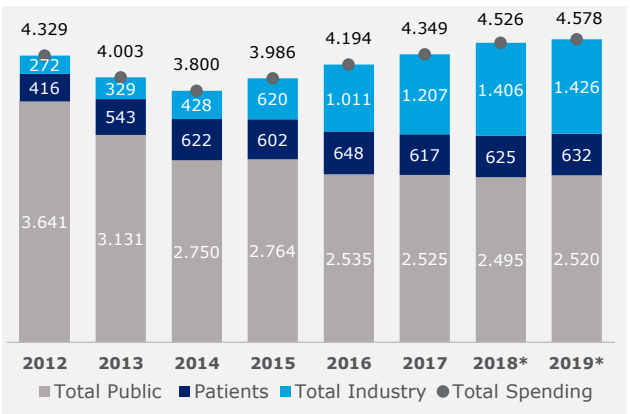
The reforms were mostly focused on fiscal adjustment and cost containment. As a result, while the private per capita pharma expenditure in 2017 exceeded by 25% the EU average, the public was below it by ~40%.

Per Capita Pharma Expenditure, GR vs EU, 2017, IOVE



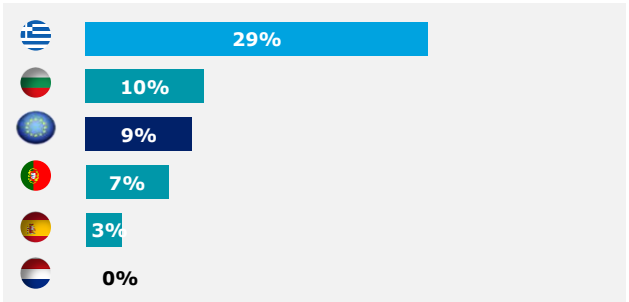
At the same time, there was a significant increase in the contributions of the pharmaceutical industry through mandatory returns and discounts ('clawback' and rebates), which were introduced in 2012 as an emergency measure. Albeit the temporary character of this measure, this payback mechanism is expected to reach 31% of the total pharmaceutical expenditure in 2019 (1).

Industry Contributions Evolution (m.€), 2012-2019, IOVE



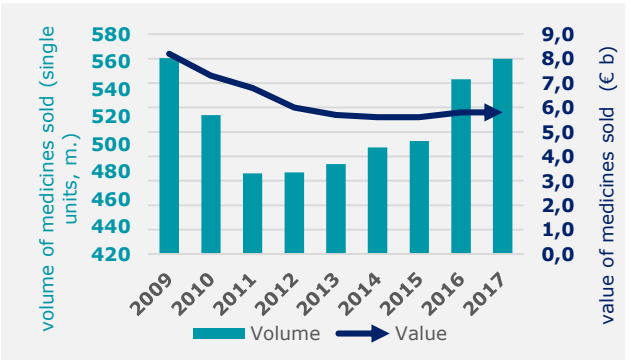
Considering the 2016 figures, Greece had the highest share of industry contributions over total pharma expenditure excl. patient contributions, compared to other EU countries, where the average was ~9% (2).

Share of Industry Contributions on total Pharma expenditure excl. patient contribution, 2016 , SfEE



On the other hand, the results where not similar with regard to the consumption of medicines, despite the various aforementioned reforms. The total value of medicines sold has decreased by 37.5% between 2009 and 2017, from 8.2 b.€ to 5.8 b.€, while the volume of single units, following an abrupt decrease in the period 2011-2013, grew in the last years back to the 2009 levels at 562 m. Single Units (1).

Medicines Sales in Greece, 2018, IOVE



The above highlight the industry's support through an exceptional financial adjustment period for the country. However, the noticeable disparity between Greece and the other EU states the importance of moving towards a pharmaceutical policy which will allow the industry to provide solutions towards a sustainable healthcare system.

(1) IOVE – The Pharmaceutical Market in Greece – Facts and Figures (2) SfEE

Current State: *Payback Mechanism & Growth Factors*

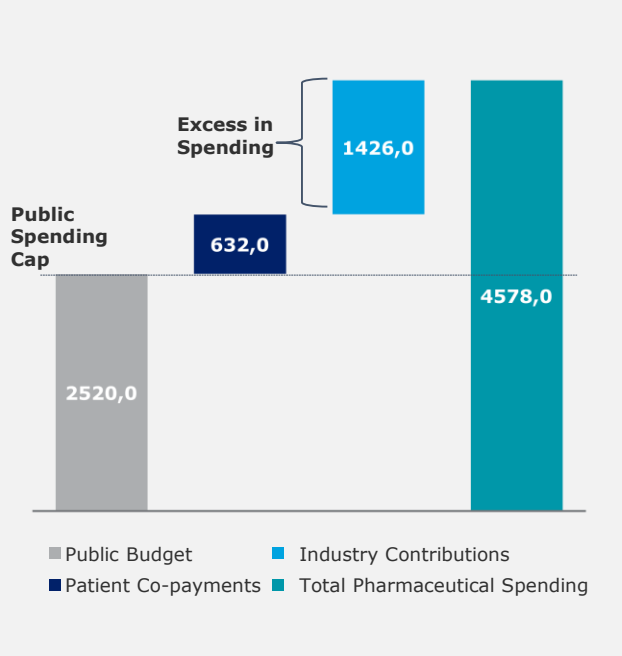
As demonstrated, the Payback mechanism was introduced in 2012 and has been growing year over year. While this, in a part, reflects inefficiencies in supply and demand, other factors as well should be considered in order to better understand the drivers, under the objective of taking the necessary actions.

Payback Growth: A Multifactorial Challenge

The way the Payback mechanism has been set up in Greece requires from the industry to contribute with a share of its revenues (based on each company's market share and growth rate) in the case of excess in the public pharmaceutical budget. While this measure has been introduced in order to prevent budget overshooting and increase predictability, pressure appears to be with the industry to serve actual population needs, as the public budget is set quite lower.

With the public pharmaceutical budget remaining, almost, at the same levels, over the last years, any increase of the total pharmaceutical expenditure contributes to the rise in the levels of the payback.

Pharmaceutical Spending Breakdown, (m.€), 2019, IOVE



Multiple factors contribute to the increase of expenditure and, thus, to the rise in the levels of the payback, such as:

Mechanisms adopted to introduce Pharmaceutical Innovation

The introduction of new innovative treatments for specific therapeutic areas, without a risk-sharing agreement, has an impact on the pharmaceutical expenditure. Innovative treatments represent an additional expense which, under the current status, adds on a predetermined, closed public budget.

Portugal has reached an agreement which includes performance-based payments on Sustained virologic response (treatment is only paid for patients who are cured), price per cure (fixed payment, independent of the duration of the treatment) and a price-volume component

Another factor related to the introduction of Pharmaceutical Innovation is the Horizon Scanning process. A well functioning Horizon Scanning process can enable pharmaceutical expenditure projections and allow for effective planning with the aim to limit the impact on pharmaceutical expenditure.

Introducing policies without considering the corresponding impact

The determination of the closed budget should consider the introduction of policies which will have an impact on total pharmaceutical spending. While the budget has been fixed in the last years, numerous policies have been introduced which are estimated to have led to increased spending – indicatively:

- Increased VAT rate for certain products
- Expiration of pricing agreements
- Reduction in co-payments for certain products
- Increased Number of Social Security Numbers

Lack of Audit Mechanisms

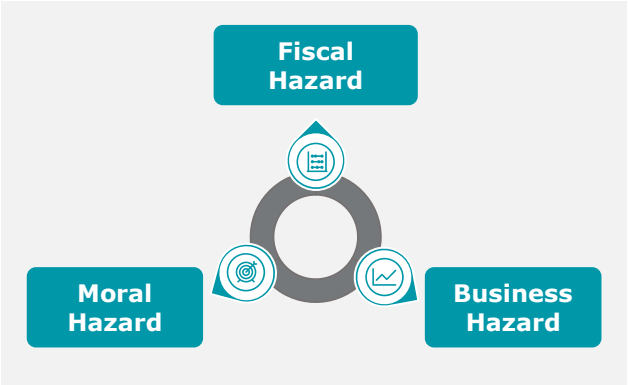
The payback mechanism lacks an appropriate audit procedure, so as to monitor performance, allow for corrective actions as well as to increase compliance from all stakeholders.

Current State: *Impact of the Payback*

The implementation of the payback mechanism, in its current format, appears to pose risks for the industry (business hazard), the wider ecosystem (moral hazard) and the public financials as well (fiscal hazard).

The implementation of the mechanism in its current setup does not support the long term sustainability of the healthcare ecosystem, as it poses risks for all the stakeholders:

Key Risks from the Current Setup of the Payback Mechanism



Fiscal Hazard

As stated in the Enhanced Surveillance Report of the EC (June 2019), *"Despite improvements in collection, the generation of new clawbacks is quite high and has been increasing over time to levels, which may soon become not sustainable. The pace of collection of clawbacks has seen an improvement in the last years, however recent measures to dilute the repayment by providers, raise concerns as to the future evolution of clawback collection and thus the liquidity of EOPYY and the deterrent to providers of facing high repayments".*

Business Hazard

Product profitability inevitably has an impact on numerous business decisions - introduction of new products in the country, planning for the necessary resources, commit for investments.

The significant business impact is apparent when considering that the payback for 2019 is expected to reach €1.3 bn., which represents an increase of €200M (18%) from 2018, while total pharma sales reached €5.8 b. in the same year (1). For the providers, the amount to be collected in 2019 is €200M, which is on the same levels as in 2018.

As described in the last Enhanced Surveillance Report (February 2020), with a view to correcting clawback trend, the authorities are planning to strengthen the efforts on the implementation of compulsory prescription/treatment protocols, which aim to curb inappropriate prescribing behaviors.

To further promote the reduction of the clawback, the European institutions have encouraged the authorities to consider a revision/redesign of the clawback mechanism to strengthen all stakeholder engagement, such as, for instance, by including an element of risk-sharing.

Moral Hazard

In principle, a payback mechanism should acts as a safety net, protecting the ecosystem from the risk of excess in spending. In the current setup, the mechanism provides no incentives or change of action to the key stakeholders, a mentality that may as well compromise the health status of the population:

The public authorities are not incentivized to implement structural reforms, which would lead to rationalizing spending and to a sustainable healthcare system, as the payback ensures neutral fiscal impact.

Patients are not incentivized to rationalize the consumption of medicines as most of the medicines are covered by health insurance while there are no campaigns for overconsumption of medicines.

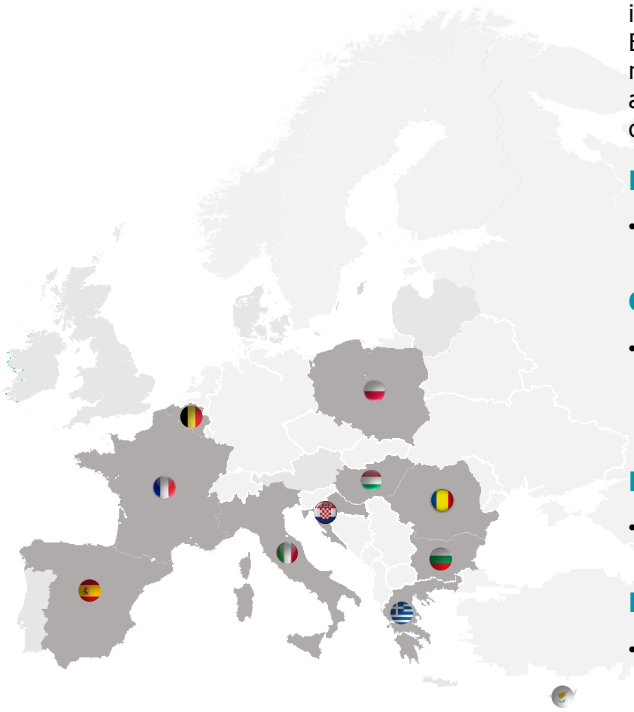
Pharmacies are not incentivized to streamline the distribution of medicines, as their remuneration is independent of the level of spending on pharmaceuticals.

Doctors are not incentivized to monitor prescription levels as they are not affected by the size of spending. The absence of an audit mechanism also contributes to that direction.

(1)) IOVE – The Pharmaceutical Market in Greece – Facts and Figures

Current State: *Payback practices in Europe*

The implementation of payback mechanisms is based on different principles around Europe. While, in many countries, payback mechanisms are more elaborate, deploying balancing mechanisms and exemptions to contain any negative effects, Greece appears to have established no such provisions.



The Payback Mechanism in Greece

The payback mechanism in Greece has been implemented in a way that is not similar to any other European country that has implemented a similar mechanism. Romania has followed the Greek example and they are the only countries without any provision on:

Payback Ceiling

- Referring to the maximum contribution by the pharmaceutical companies

Co-Responsibility with the State

- Referring to the reciprocity principle and acknowledgment by the State that they are partly responsible for the excessive spending on medicines

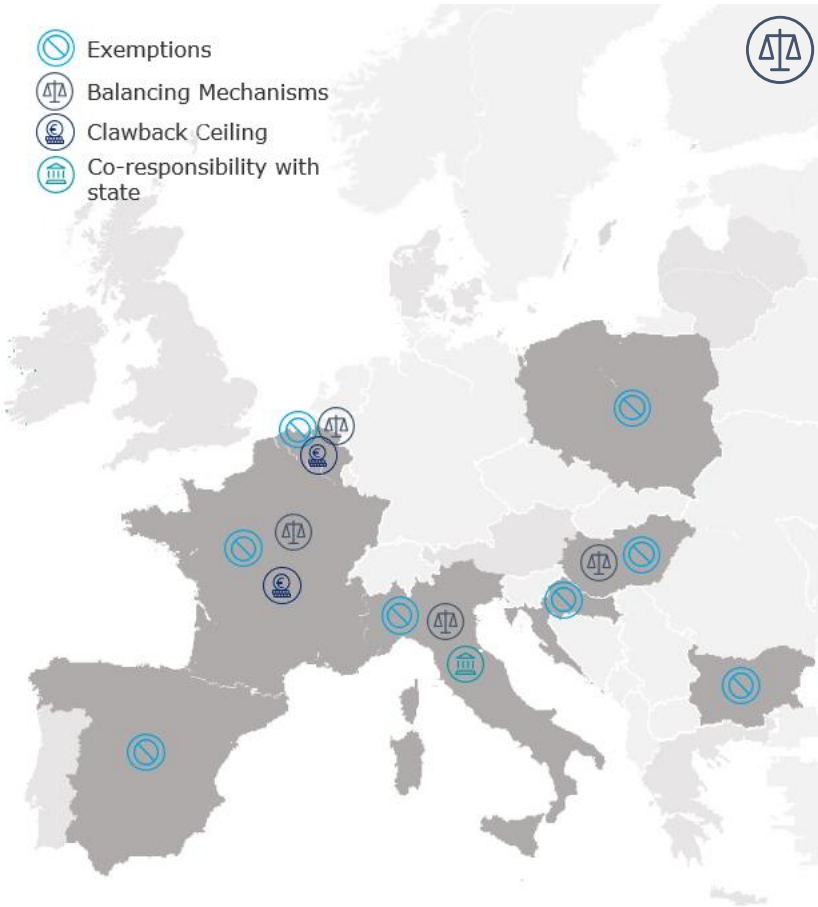
Balancing mechanisms

- Referring to the ways for adjusting the payback in order to eliminate the negative effects of clawback

Exceptions

- Referring to the different items of the budget removed from clawback calculations (i.e. vaccines)

Countries	Payback Ceiling	Co-Responsibility with State	Balancing Mechanisms	Exceptions
				✓
		✓		✓
	✓		✓	✓
	✓		✓	✓
		✓	✓	✓
				✓
				✓
			✓	✓
				✓
				✓



Balancing Mechanisms

Industry pays its contribution in the form of taxes on turnover after neutralization, a procedure which involves predefined reasons for potential exceedance for which industry is not responsible.

Never exceeded the pharmaceutical budget so far thanks to other mechanisms allowing to balance the budget.

Clawback can be reduced for companies selling medicines against HEPC if certain conditions are met in terms of turnover and the companies sign a convention with the Economic Committee for Health Products (CEPS).

Establishment of two funds: innovative drugs (500M) and oncology innovative drugs (500M). If expenditure exceeds the fund, the overspending is added to non-retail medicines.

For the outpatient market, 100% of the overspent is distributed to pharmaceutical companies, wholesalers and pharmacists, proportionately to their share of overspending.

Payback Ceiling

Maximum contribution for companies is 2.5% of the pharmaceutical budget.

Maximum contribution for companies cannot exceed 10% of company's turnover.

Co-responsibility with state

Both parties (industry and government) contribute to the financing of overspending and healthcare budget is reviewed each year based on actual last year's expenditure.

For the inpatient market, the overspent is borne by both industry and regions (50% share each).

Exceptions

Orphan drugs, blood products, drugs in hospital forfait

Multiple source products

Prescription medicines

Generics and orphan drugs (in the limit of 30M)

Innovative and orphan medicines

Hospital medicines and medicines with risk sharing mechanism set

Generics

Reduction of clawback for R&D investments in the country

Products derived from human blood or plasma and vaccines included in the NIP

Current State: *Stakeholders' View*

A number of stakeholders, covering the entire ecosystem, contributed with their views in order to holistically assess the impact of the legislated reforms and on the current state of the pharmaceutical policy.

Achieving the required engagement with key stakeholders, from the entire value chain, was critical in the effort to set up a holistic vision for the development of a sustainable pharma policy in Greece.

While the views were focused on the appropriate area of expertise, this dialogue also covered the current state of the pharmaceutical market and the impact of the policies which have been introduced over the past years.

The conducted meetings involved: Executives of pharmaceutical companies, representatives of pharma associations, medical and patient associations, professors focusing on Pharma and Healthcare policy and Institutional Bodies from Greece and the EU.

Key Messages (indicative)

A COVID-19 Perspective

A COVID-19 Perspective: *Addressing the Crisis*

The COVID-19 outbreak has evolved into an unprecedented challenge for the entire world. The pandemic is affecting many aspects of everyday life and will impact the economy, the society, as well as, the healthcare systems.

COVID-19

Starting first from the Wuhan region in December 2019, **the coronavirus pandemic has spread around the world**, causing one of the biggest global crises of recent times. In an effort to restrict the transmission of the disease in the community, many countries have imposed **lockdowns**, restricted freedom of movement and introduced strict **social distancing measures**. Moreover **non-essential economic activities** have been put on halt and **travel bans** have been introduced. The **consequences of the pandemic are dramatic**, not only for healthcare systems, but also for economy, politics and society as a whole. The impact of the pandemic is expected to be severe even in the best case scenarios.

3 Main Scenarios for the Global Economy(1)

	Mild	Harsh	Severe
	-5%	-8%	-10%
	-5%	-8%	-10%
	+3%	+1%	-3%
	0%	-3%	-6%

No economy or industry will escape the disruptions caused by Covid-19, although **each country will face unique challenges** based on the importance of certain sectors to the national economy.

Greece has some distinct characteristics such as **increased reliance** on Tourism (est. 12% direct impact on the country's GDP), relatively small industrial production and negative balance of trade. Moreover the Greek economy is **mainly driven from private consumption**. While the crisis is anticipated to have a positive effect on sectors like the Life Sciences and Media & Digital Entertainment, sectors like Tourism, Aviation, Retail are expected to face significant challenges in the following period.

Overall in Greece, the National Healthcare System **managed to respond to the crisis** without overwhelming the Public Hospitals and, considering the communicated prevalence of COVID, the country appears closer to a 'Mild' economic scenario.

*Greece is expected to face a **6% decline** in GDP in 2020, followed by a **growth of 6%** in 2021* (2)

Responding to the Crisis

The **response** to this crisis has been **unprecedented**. Measures aiming to address the continuing effects of the coronavirus spread and to facilitate the return to normality, from a social and financial perspective, have been adopted internationally. On EU-level, as Decline in European GDP in 2020 is expected to exceed the recent financial crisis, **fiscal rules have been eased** thus countries can allocate resources based on emerging needs, without having to meet the targets and requirement previously set. Consensus has also been reached regarding the creation of an **Emergency Fund of €500b**. Greece can secure **financing of up to 2% of the GDP** through ESM limited to covering health-related expenses in response to the coronavirus, directly or indirectly.

The Greek Government moved quickly and adopted several measures to contain the spread of the virus, to support the economy and to strengthen the National Health System. Lockdown was enforced for 6 weeks and various measures, of **€24 b. in total**, aiming to tackle the effects of the pandemic were taken. The measures were related to:

- extensions / suspensions of tax collection
- insurance contributions
- labor legislation
- issues of bank loan payments / financial installments, focusing on the facilitations provided for businesses.

(1) Deloitte Analysis (2) EBRD

Impact on Healthcare Systems Worldwide

COVID-19 is expected to have a **profound impact on healthcare systems** worldwide and affect various areas of the healthcare systems both in the short term and in the long term.

Focus will be put on patients as stakeholders across the entire health care ecosystem need to continue to support efforts to manage the pandemic through education of patients. Visits to hospitals will be reduced and lower acuity elective cases are likely be deferred during peak periods.

Protecting the health of their workforce will be paramount for health care organizations as well. Moreover, the role of functions like primary care will be reevaluated.

The pandemic is also highlighting the need for health care **organizations to review and adapt their care delivery models**, including further moves towards a virtual care environment.

Healthcare **funding will also be affected** as the easing of the fiscal rules has led countries to reevaluate their health spending while strong collaboration between States and Industry is strongly suggested as well.

Greek Healthcare System

The Greek Ministry of Health **acted rapidly to support and upgrade the National Health System**. The recruiting of medical personnel is in progress along with a targeted increase in ICU capacity in Public Hospitals.

The **redesign of Primary Care** has also been declared as a strategic objective for the Ministry and, on this front, **500 mobile sampling and testing units** were deployed across Greece.

- Increased capacity of **ICU beds** from **565** to **1,015**
- Recruiting of **4,150** doctors and Nurses (1)

Area	Short-Term Effects	Long-Term Effects
Reprioritization of patients	• Postponement of some elective care • Reduction in visits	• Backlog of patients for elective care • Amplified severity of patient conditions • New views on "essential" services
Workforce	• Greater stress, pressure and illness on workforce	• Review of some healthcare roles (e.g. primary care)
Technology / Innovation	• Increased use of technology in patient interactions	• Permanent shift in primary care delivery models • Greater understanding of infectious diseases and treatments • More efficient processes for introduction of new drugs and treatments
Funding	• Increase in funding to healthcare services for short-term provisions, etc. • Reallocation of budgets to "front-line"	• Greater scrutiny of healthcare spending (especially across high-priority areas) • Increased funding for prevention of infectious diseases and stockpiling • Greater need for value and increased use of data to define value of the health system
Regulation	• Regulators prioritizing resources towards Covid-related tests, vaccines, treatments, etc.	• Switch in regulator priority framework and resource allocation to address most important issues at the time • Potential for greater collaboration / sharing of resources between regulators
Mental Health	• Rise in demand for emergency healthcare	• Increase on patient numbers due to the lockdown effect

(1) Ministry of Health

A COVID-19 Perspective: *Impact on Pharma*

The pandemic is affecting the whole pharmaceutical ecosystem and focus has shifted on biopharma companies which have been racing to deliver needed supplies and develop new vaccines and novel therapeutic interventions.

Once this health emergency passes, pharmaceutical companies – globally and in Greece - are expected to find themselves operation on a different environment. The response to this global outbreak is already changing the pharmaceutical ecosystem, mainly, in the following areas:

Focus on Vaccines & Prevention

Lessons learned from the COVID-19 pandemic could lead pharmaceutical companies to shift R&D investments to prevention of infectious diseases and Government to allocate more resources on prevention to ensure the resilience of Healthcare Systems and avoid financial rescue packages.

Regulatory Flexibility

We are seeing unprecedented levels of collaboration between governments and pharmaceutical companies to accelerate clinical trials. Private-public collaborations are expected to increase in the years to come.

Supply and Demand

The pandemic has caused significant disruptions in the supply chain from restriction in exports, to quarantines and worker illness and to closing the closing of factories and manufacturing activities.

Once effective COVID-19 antivirals have been identified and approved, drug manufacturers will need to rapidly scale up production and distribution capabilities to meet a massive demand. Moreover, patients may choose to increase the purchases of certain drugs as a response to the uncertainty.

Digital Acceleration

The adoption of Digital Technologies, from both Governments and Pharmaceutical companies has been accelerated due to the pandemic.
In Greece, ministries of Digital Governance and of Health launched "e-prescription", a platform where citizens/patients, doctors and pharmacists will make use of modern technologies to get a prescription without paying a visit to the doctor or to a hospital.

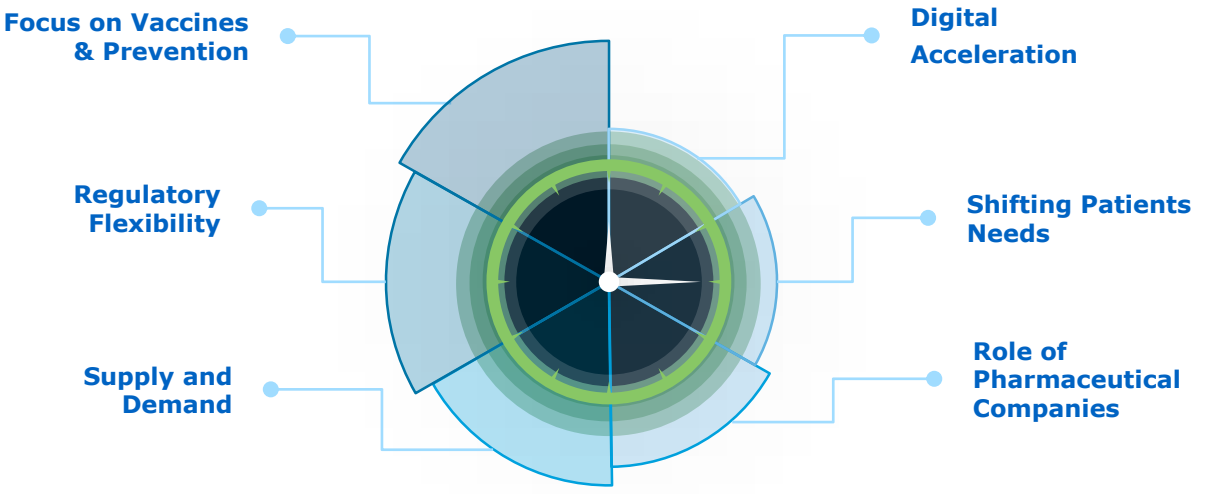
Shifting Patients Needs

Out of Pocket payments are expected to put further pressure on patients. This effect will be even more prominent in countries like Greece, where OoP are significantly high. Moreover, the need to explore new ways of delivering clinical supplies and of connecting with patients arises, as patients may be hesitant to visit pharmacies and hospital facilities.

Role of Pharmaceutical Companies

The pandemic has shifted the focus on pharmaceutical companies. Companies foster collaborative research, aiming to identify any suitable assets in their libraries that could be utilized to develop diagnostics, vaccines and treatments in the fight against coronavirus.

In Greece, Pharmaceutical companies have been in the forefront of the fight against COVID-19 either by launching the production of a drug cited as possible treatment of the disease or by offering hospital equipment, as well as medical supplies and sanitary material to the Ministry of Health.



A COVID-19 Perspective: *What's Next?*

The decisions made during this time will probably shape the world for the years to come. While it will take time and effort, this crisis reinforces the need for changes in the market and may well become an opportunity to move forward.

Critical Areas for the Next Day

Short - Term

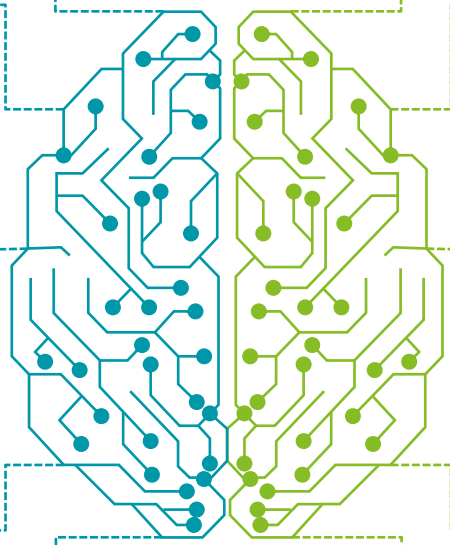
Resilient Supply Chain
The entire pharmaceutical value chain should be supported to ensure availability of products and to minimize disruptions.

Innovative Treatments
The market should have adequate room to welcome new treatments, considering the pipeline of the companies as well as in the context of COVID-19

Transition to Virtual Care
The exploitation of platforms and data will support the transition to Digital Healthcare.

Focus on Vaccines
The market should be prepared to support an expected increase in vaccines, due to COVID-19 and to increase adherence to vaccination guidelines

"Restart" Greece
A patient centered and adequately financed health system will support the country's efforts to be established as a safe destination for travelers



Long - Term

Resilient Health System
The crisis highlights the need to strengthen primary care in the effort to relieve pressure from hospitals.

Promote Investments
Considering the economic impact, the country should further leverage the opportunity to attract investments in the Healthcare sector.

Pharmaceutical Exports
The contribution of the pharmaceutical sector on exports should be further increased in order to balance the expected deficit in other sectors.

Pharmaceutical Production
A strong pharmaceutical sector will contribute to creating and maintaining job positions.

Collaboration
The current healthcare challenges highlight the importance of fostering a collaborative ecosystem among all stakeholders.

The Way Forward

The Way Forward: *Setting the Vision*

The Vision for a Sustainable and Patient Centered Pharma Policy is designed with a view on achieving specific outcomes through enabling the successful implementation of the outlined policies and removing the barriers that have hindered success in previous years. It also represents the long term ambition for a pharmaceutical industrial strategy aligned with government priorities.

Vision for a Sustainable and Patient Centered Pharma Policy in Greece: Core Values

Promote Long-Term Sustainability

Start working on external environment and structural changes that will enable optimal system configuration and improve efficiencies

Put Patient Benefit in the Heart Of Decision Making

Use criteria of access, quality and value for money in the process of decision making

Reduce Complexity and Promote Standardization

Simplify processes, governance and regulatory framework in order to standardize environment of operation and provide stability to all stakeholders

Increase Transparency In Process and Decision Making

Standardize and share methodologies and decision making criteria to enable cultural change and foster relationships of trust amongst stakeholders

The Way Forward: *Framework for Action*

In order for the Vision outcomes to be achieved, key proposed measures are organized under four levers of action. The execution of the framework requires the existence of three main key enablers.

The Framework for Action Consists of Four Basic Levers:

Key Enablers for the Execution of the Framework:

Governance

Promote the right governance framework to create standardization, simplify complexity and create clarity and purpose in the decision-making process.

People & Processes

Align the people with the necessary skills to the right priorities to expedite execution and continuous learning and improvement.

Data & Technology

Leverage technology to create linkages for collaboration and data to create insights that will help foster rational decision-making, transparency, trust and collaboration.

Rationalize Demand

- Strengthen the role of primary care with the aim to increase gatekeeping and, thus, the efficiency of the system. While a relevant initiative was initiated in the past year, this should be revisited and optimized, so as to reduce the pressure on the hospitals, a need which was further highlighted during the current pandemic
- Finalize the clinical protocols for the main therapeutic areas (TAs) and 'lock" them in e-prescribing
- The generics and biosimilars policy should be revisited through examining the set targets, the licensing procedures and the pricing mechanisms. A strategic approach combining the envisioned penetration at the appropriate price levels, will create further savings which may be invested in innovation.
- Establish a reliable mechanism to provide the appropriate medicines to the uninsured population
- Establish a reliable mechanism to support an expected increase in vaccines, due to COVID-19 and to increase adherence to vaccination guidelines
- Utilize tools like physician benchmarking to incentivize prescribing rationalization
- Create patient registries and provide relevant access rights
- Create minimum data specification and dataset for epidemiological data
- Incentivize physicians to update personalized electronic integrated health records
- Link diagnostic outcomes to e-prescribing system
- Audit e-prescribing system and create feedback loop and continuous improvement framework
- Promote patient education on prevention and shared decision making through physician community

Rationalize Supply

- Solidify the role and mandate of an HTA organization
- Review the staffing and the process (e.g. inclusion of Generics, accelerated access for innovative products, criteria of evaluation) of the HTA body
- Establish transparent criteria for the evaluation of market entry and evidence based negotiation process for reimbursement
- Leverage the tendering process for hospitals
- Create a distinct process for the review of medicines in the positive list
- Considering the need to avoid frequent modifications, review the methodology for a stable methodology for the calculation of reference pricing, clawback and rebates
- Establish a central data warehouse in order to ensure that all stakeholders leverage the same data for price and volume, enabling smooth negotiations
- Train and engage subject market experts (SMEs) as assessors in the HTA body
- Explore Managed Entry Agreements in order to increase risk sharing, but also for facilitating patients' access to innovative medicines
- The end to end supply chain should be supported to ensure availability of products and to minimize disruptions caused by the COVID-19 outbreak

Promote Innovation

- Provide Incentives to all stakeholders (Industry & Hospitals) for investments in Clinical Trials
- Establish innovation fund for new and innovative treatments
- Ensure budget availability for innovative medicines in the context of COVID-19, as well as for new treatments currently in the pipeline of companies
- Create a dedicated task force for the growth of clinical trials in Greece
- Industry to create apprentices to promote local skills e.g. on bioinformatics, regulatory affairs, clinical trials
- Create RWE infrastructure in a CoE
- Establish an Horizon Scanning process in order to proactively calculate and allocate the necessary financial boost for new innovative therapies on annual basis
- Improve public system's commercial capacity and skills
- Comprehensive long-term policy to promote Greece as a leading destination in South East Europe for R&D investments
- Provide incentives for manufacturing activities
- Attract investments in the Healthcare and Pharmaceutical Sector so as to support the country's effort to be established as a safe destination for travelers on and increase the contribution of the sectors to the economy

Promote Effective & Fair System Oversight

- Enhance EOPYY's purchasing power and strengthen single payer role
- Create a clear organogram of organization hierarchy, role and powers of EOPYY
- Introduce the reciprocity principle in clawback and rebate payments in order to increase transparency and improve the pharma market sustainability
- Set annual targets for clawback reduction through spending monitoring committee
- Recognize the notion of Co-responsibility and address it through a collaboration scheme with clear targets
- Promoting interoperability between the systems of all public stakeholders involved in the healthcare value chain.
- Establishment of a digital governance unit
- Utilize platforms and data to facilitate the transition to Virtual Care, supporting the response to COVID-19
- Measure expenditure and cost-savings potential based on commonly agreed data sets, sources and methodology
- Train people in key roles in data analysis, interpretation and data-driven decision making
- Engage with the Ministry of Finance, the Ministry of Development and the EU partners
- Initiate auditing processes
- The current healthcare challenges highlight the importance of fostering a collaborative ecosystem among all stakeholders

The Way Forward: *A Set of Initiatives*

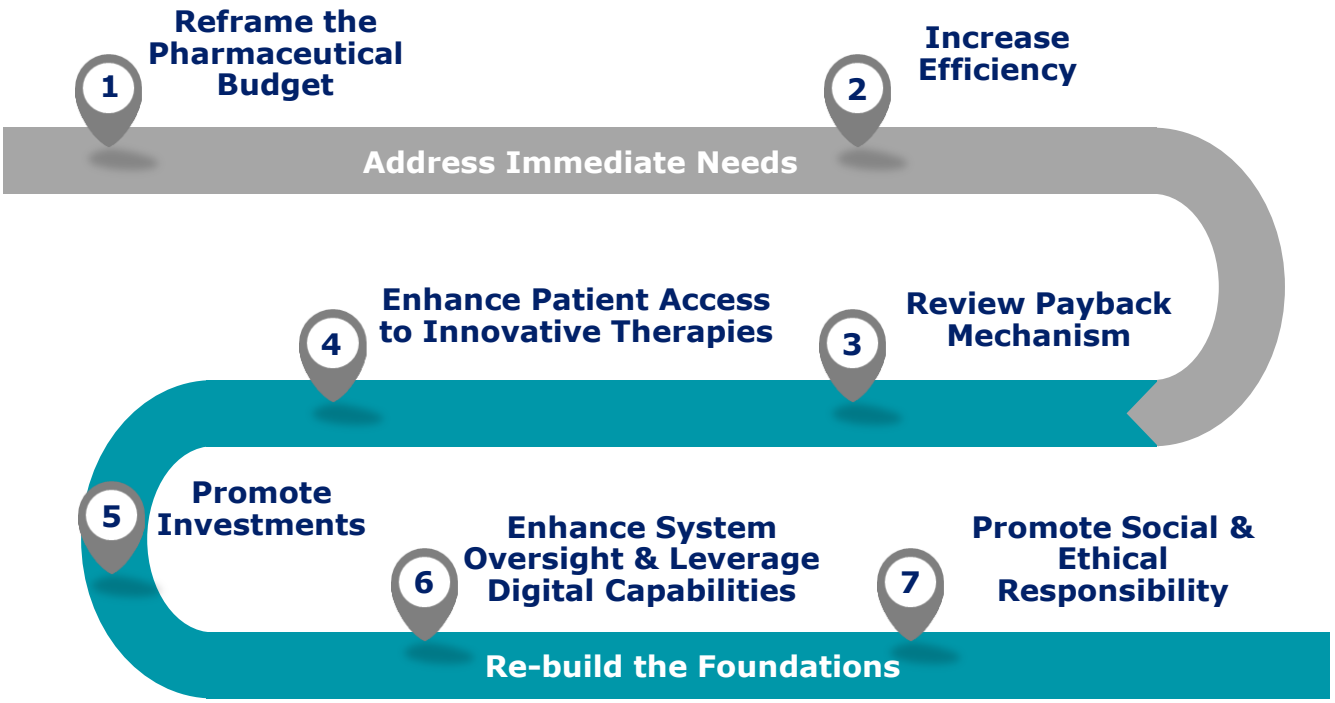
Building on the identified actions, a set of seven specific initiatives emerges in order to deliver the holistic targeted Vision. A Roadmap has been developed, with the purpose of prioritizing the initiatives and facilitating the implementation.

In order to facilitate the **move towards the suggested vision** of a Sustainable and Patient Centered Pharmaceutical Policy, seven initiatives have been developed, based on the actions highlighted under the four pillars of the framework, and have been **prioritized**, with the aim to create **a roadmap** for achieving the targeted vision.

The proposed initiatives are grouped into two major categories:

- Initiatives which focus on addressing the **immediate need** for controlling pharma spending and rationalizing the allocation of resources with the aim to **ensure a neutral budget impact**.
- Initiatives which aim to support in **re-building the foundations** of the ecosystem (key organizations, information systems, processes, mechanisms, social role of the industry).

Proposed Initiatives



A Roadmap Towards Achieving the Vision

The **proposed initiatives** should not be viewed as standalone interventions, as various **interdependencies exist** between them. A **holistic approach should be adopted** in order to achieve the targeted vision. For their **successful** and **effective implementation, a prioritized roadmap should be put in place.**

Initiative 1. Reframe the Pharmaceutical Budget

Define a pharmaceutical budget that covers the needs of the population comprehensively, considering the current and immediate future needs of the population and the available products. The COVID-19 outbreak highlights the importance of adequate funding.

The budget should have a horizon of 2 to 4 years, while a process of annual review should be established, as well as a re-forecasting process.

The budget needs to consider both inpatient and outpatient needs and may be based on:

- Historical figures
- Epidemiological data
- Introduction of new medicines and the expiration of patents, both in terms of inpatient and outpatient needs
- A horizon scanning process which will allow for proactive calculation and allocation of the financial boost required for new innovative therapies
- Timely introduction of innovative treatments in the context of health emergencies, a need highlighted by the recent COVID-19 pandemic.
- Tools to enhance flexibility, such as developing additional and separate fund for prevention (vaccines) that will allow better control and financing in order to cover the expected increased demand due to COVID-19
- A policy regarding generics and biosimilars
- Repricing and reimbursement policies

The budget should consider not only the values but also the volumes of the medicines, in order to align with consumption targets.

Considering the growth of the pharmaceutical budget in the last years and the expected trend in the post COVID-19 era, it is estimated that an increase of over €200 m. per year should be considered (this corresponds to an annual rate of 3%-4%, which is in line with the global trends).

Furthermore, a detailed development of the wider budget, will allow to approach in a more rational way the allocation between the public, the industry and the patients.

In this direction, a phased approach should be considered, in order to bring Greece (where public contribution has decreased from ~69% in 2015 to ~55% in 2018) closer to the EU average (~64% in 2018).

This initiative not only will facilitate better control, but will also provide the unique opportunity to comprehend the health needs of the population, while it will also allow long term planning for all stakeholders.

Furthermore, this initiative helps in putting the patient in the center as it will provide the opportunity to better address unmet needs, to introduce innovative treatments, while aiming to control the out of pocket contribution of the patients.

Initiative Characteristics

Impact on public budget	+ € 150-250 m. annually for 3 years	**Time to Implement**	1 year for full implementation
Supports Vision			

Initiative 2. Increase Efficiency

Promote a new modus operandi for the prescription of medicines in order to rationalize consumption for both the retail and hospital medicines. This should aim at enabling prospective and effective management of resources, as well as to improving purchasing process.

The successful implementation of the initiative relies on engaging all stakeholders on:

i. Finding ways to leverage the depth of data sources across the system and

ii. Providing incentives to all stakeholders, including doctors, pharmacists and patients which will lead to achieving common goals.

Key actions should include:

- Review spending patterns throughout the value chain in order to identify inconsistencies – leveraging patient patterns which will cover the most common TA's in Greece.
- Leverage clinical protocols, designed by specialty doctors for each category and expanded to cover all the TAs. The protocols should be "locked" in e-prescribing, so as to safeguard the efficiency in their use, while incentivizing good practice.
- Establish auditing processes in order to monitor adherence to prescribing behavior throughout the value chain.
- Strengthen the role of primary care with the aim to increase gatekeeping and, thus, the efficiency of the system.
- Relieve pressure from hospitals and acute care and move towards a more resilient Healthcare System
- Review and optimize public tendering processes (both for inpatient and outpatient spending).
- Review the clusters of insured groups with pharma coverage, so as to better monitor performance and identify potential areas of misconduct.
- Develop monitoring tools, such as physician benchmarking tools (for the general practitioners) and use incentives aiming to sustain waste and promote rational prescribing.
- Promote patient education on prevention and shared decision making in the treatment process.

The objective should be set on levels that would neutralize the needed increase in the budget, as described in Initiative 1, for a period of at least 2 to 3 years. This requires a saving of €230 m. per year or ~5% of the annual pharmaceutical budget – a figure which is considered achievable, taking into account the OECD discussed data (*as much as 20% of healthcare spending may be considered as wasteful*), but also the results of relevant efforts in the private sector, as well as in the public sector (38% savings on medical goods achieved with the Healthcare Procurement Committee – EPY).

As such, this initiative should constitute the cornerstone of a plan for a sustainable healthcare, as it would provide funds that could be re-invested in the sector in the form of further supporting patient centricity, innovation and growth.

Furthermore, these actions will re-establish transparency and trust between stakeholders and will facilitate taking more accurate, reliable and valid decisions.

Initiative Characteristics

Expected Outcomes	Targeting a 5% saving per year, would yield a benefit of ~€230m.	**Time to Implement**	2 to 3 years for full implementation
Supports Vision			

Initiative 3. Review the Payback Mechanism

Review the payback mechanism so that it works as an incentive to reduce excessive spending across the system, while also maintaining the sustainability of the industry.

Key objectives of this initiatives should include:

- Commit and safeguard the fair contribution by all parties in funding the overspending
- Foster the collaboration between the industry and the government by promoting through a mix of actions the reciprocity principle
- Ensure transparency on the allocation of revenue collected
- Achieve the aspired control of overspending while minimizing the direct business impact

Key actions to be considered include:

- Establish a risk sharing mechanism, based on the principle of co-responsibility. While the payback for the industry will cover a pre-determined percentage of overspending, a subsequent percentage will be allocated to the state – thus providing the incentive for further controlling and auditing the expenditure.
- Leverage different types of provisions taken by other countries, such as exemptions from the clawback calculation, mechanisms that could be used to adjust the payback in order to eliminate the effect from clawback and setting a contribution ceiling by the industry.
- Reconsider the methodology of application of the payback mechanism – a part of the payback could be applied in the form of a tax fee, thus achieving the same fiscal result while reducing the impact on revenues.
- Aim to gradually align the level of payback with the EU average. While in 2018, as presented, this is estimated to be at ~28% of the total pharma expenditure, this may be driven closer to the EU average (in 2016: 9% excl. patient contribution).
- Leverage specific bodies to frequently monitor and report progress on spending, as well as to take the necessary measures in order to keep the market on track.
- Ensure the reciprocity of the Payback mechanisms by using the contributions of the industry in improving the efficiency of the healthcare system.

It should be noted that the gradual decrease of the payback, as a % on total expenditure, will be facilitated through setting a public budget that will incorporate adjustments for growth (Initiative 1), as well as through tackling wasteful spending (Initiative 2).

It is expected that this initiative will have a significant impact on the sustainability of the participating businesses, while it will also address the various associated risks (fiscal / moral hazard).

Initiative Characteristics

Expected Outcome	Increase sustainability, reduced risks	**Time to Implement**	Up to 1 year for full implementation
Supports Vision			

Initiative 4. Enhance Patient Access to Innovative Therapies

Ensure the affordable, equitable and timely access of innovative therapies to the Greek market, via an effective, dynamic and continuous Health Technology Assessment process. Re-organizing the HTA process is an initiative focusing on achieving outcomes in a short-term period, in an effort to reinstate the introduction of new products to the Greek market, with an emphasis on pharmaceutical innovation.

The actions required in order to ensure the successful implementation of this initiative include:

- Solidifying the role and the mandate of the HTA body by clarifying whether its role will be advisory or decisive.
- Ensuring formal patient involvement in the HTA process.
- Introducing prioritization guidelines and identifying the scope of the medicines to be assessed. More specifically, prioritization guidelines should be put in place, taking into account factors like the severity of the disease or the levels of unmet need. Generics and biosimilars should be excluded from the HTA process as they do not represent therapeutic advances or innovations.
- Establish a Horizon Scanning process which will allow for proactive management of resources and better predictability of future needs.
- Engaging the appropriate staff (both assessors and administrative employees) and Subject Matter Experts based on the anticipated workload.
- Leveraging data, available resources and expertise from other EU countries in an effort to promote efficiency (e.g. EUNetHTA).
- Setting pragmatic timelines for both the assessment and the re-submission, based on best practices used by other HTA bodies which are assessing similar amount of products with similar resources.
- Promoting transparency in the process of decision making, ensuring that information is available to all relevant stakeholders and introducing templates and clear criteria for both the submission and the assessment.
- Establishing a separate process for the review of the medicines that are already in the positive list.
- Using Managed Entry Agreements, which can ensure affordable access to medicines in the market.
- Introducing mechanisms to facilitate the funding of innovative mechanisms (e.g. Innovation Fund), based on their level of innovation, as assessed by the HTA.

The proposed initiative will facilitate the introduction of innovative products to the Greek market and as a result will contribute towards a more patient centered system. Moreover it will ensure that in times of health emergencies the access to innovative treatments will be secured and facilitated. Patients will have access to innovative therapies as waiting times between marketing authorization from EMA and access to the Greek market will be reduced.

A solid HTA process will provide the framework to the government to optimize the use of scarce resources and the stability regarding Market Access for the Pharmaceutical companies, thus contributing to reducing complexity and promoting standardization.

Initiative Characteristics

Expected Outcomes	Decreased Patients' Waiting Time to Access Pharmaceutical Innovation	**Time to Implement**	Up to 1 year for full implementation
Supports Vision			

Initiative 5. Promote Investments

Create an environment that allows planning, facilitates development and attracts investments with the aim of achieving overall economic & business growth. The developed policies should have a multi-year horizon and should be reviewed annually following Greece's economic performance.

The creation of a favorable environment can be achieved via:

- Setting the right conditions to make Greece an attractive location for investments in the field of healthcare and life sciences. Investments may include R&D centers, manufacturing sites and Centers of excellence.
- Creating a dedicated task force for promotion of clinical trials and providing incentives for investments in that field. Incentives should be provided to both the pharma companies and to the hospitals' management.
- Streamlining the process of initiating Clinical Trials and reducing bureaucracy.
- Ensuring appropriate information sharing on the ongoing clinical studies in Greece and abroad, in order to better connect with the research community and the patients.
- Encouraging the national research and development in the field of pharmaceutical products.
- Creating the appropriate framework to support manufacturing activities with the aim to attract foreign investments.
- Support the exports of Generics with the aim to improve the trade balance of pharmaceutical products.
- Setting a stable business environment that enables accurate planning and increases the country's credibility.

A comprehensive policy to accelerate developments and promote growth will have a positive impact on the sustainability of the system and will facilitate the move towards a patient centered system.

In the context of COVID-19, promoting investments in the pharmaceutical sector is expected to support the country both in the short and the long term. Not only will a patient centered and adequately financed sector will support the country's efforts to be established as a safe destination for travelers (thus supporting key economic sectors such as tourism), but will also contribute to creating and maintaining job positions. Furthermore, the sector may further leverage its exporting activity, possibly balancing the expected slowdown in other sectors.

Overall, this initiative aims at promoting Greece as a leading destination in South East Europe for investments in healthcare and at strengthening the presence of pharmaceutical companies in the Greek market. Both of these outcomes will also strengthen the pharmaceutical sector's contribution to GDP and to employment, thus leading to sustainability.

Patients will also benefit significantly from the boost in the number of clinical trials as they will have improved access to potentially life saving therapies and will also be able to play a more active role in their health care.

Initiative Characteristics

Expected Outcomes	Business & Economic Growth, Support of R&D	**Time to Implement**	1 to 2 for full implementation
Supports Vision			

Initiative 6. Enhance System Oversight & Leverage Digital Capabilities

Create a clear governance structure for all the organizations involved in the Greek healthcare value chain and leverage digital technologies in increasing the overall efficiency of the value chain.

Between the two parts of this initiative, the creation of the governance structure should be prioritized, as it is considered a prerequisite for the effective implementation actions regarding leveraging digital technologies.

The implementation of this initiative can be achieved via:

- Clarifying the role and establishing clear responsibilities for all the organizations in the healthcare value chain (EOPYY, IDIKA, MoH, Hospitals, YPE, etc.).
- Promoting interoperability between the systems of all public stakeholders involved in the healthcare value chain.
- Establishing a digital government unit responsible for planning, coordinating, implementing and monitoring digital transformation initiatives.
- Using data analytics to identify past trends in pharmaceutical spending and enable expenditure projections.
- Leveraging digital technologies to audit ePrescription and control induced demand by ensuring the use of the appropriate therapeutic protocols.
- Adopting digital tools in the HTA process, with the aim of creating a paperless process.
- Creating integrated healthcare records and linking diagnostics to ePrescription.
- Establishing of a central data warehouse to act as a single source of truth

The interoperability of all the systems and integration across all stakeholders is critical in order to be able to leverage the power of data collection across all stakeholders.

This initiative is expected to have a positive impact in terms of the transparency of the system, as digital technologies can enable data collection and data-driven decision making. What is more, a clear governance structure will increase accountability contributing, as well, to a more transparent healthcare system.

As the COVID-19 pandemic has accelerated the transition to Virtual Care, the introduction and exploitation of digital platforms and data is critical in the country's effort to move towards a Digital Healthcare delivery model.

Process standardization will be also facilitated by simplifying processes, reducing complexities and enabling more efficient communication between various stakeholders.

More importantly, the structured and secure communication between the various stakeholders, including the exchange of information, will assist in fostering a culture of collaboration among the various stakeholders, a key factor in addressing efficiently major healthcare challenges.

Initiative Characteristics

Expected Outcomes	Effective Governance Structure	**Time to Implement**	1 to 2 years for full implementation
Supports Vision			

Initiative 7. Promote Social & Ethical Responsibility

Promote a cultural shift regarding the role of pharmaceutical companies in the Greek healthcare environment. Pharmaceutical companies need to engage actively in Corporate Social Responsibility activities and safeguard ethical practices in order to counter negative perceptions and facilitate the move towards a more sustainable system.

This shift can be achieved by:

- Promoting a culture of proper use of medicines from the patients – in terms of adherence, reduction of waste, acceptance of generics and proper consultation of doctors.
- Designing and implementing targeted campaigns towards rationalizing the patients consumption and adherence patterns.
- Safeguarding ethical business practices, under a specific Code of Ethics, so as to eliminate effects of induced demand.
- Establishing an efficient and reliable mechanism in order to provide the appropriate medicines to the uninsured population holding valid Social Security numbers (AMKA).
- Working collaboratively with the State in order to co-design, support and lead initiatives promoting prevention and initiatives targeted to socially vulnerable groups in ways which are transparent, efficient and measurable.
- Participating in partnerships with the State, aiming to bridge gaps and address inefficiencies in the system with the use of digital solutions in hospitals.

It is critical to ensure that all social responsibility actions undertaken by the various players of the industry are aligned and coordinated under "one voice" in order to avoid misinterpretation and ensure the expected outcomes.

This initiative will contribute towards patient centricity as universal access for all population is promoted via provisioning of medicines to uninsured population. Also, any digital solutions implemented by the industry, in partnership with the State, increase patient experience and satisfaction.

The sustainability of the system will also be positively affected by the implementation of this initiative. Campaigns regarding the use of medicines and the can lead to rational consumption of medicines and increased adherence, thus limiting wasteful spending and contributing to sustainability.

Initiative Characteristics

Expected Outcomes	Reduced Waste and Improved Access to Healthcare	**Time to Implement**	1 to 2 years for full implementation
Supports Vision			

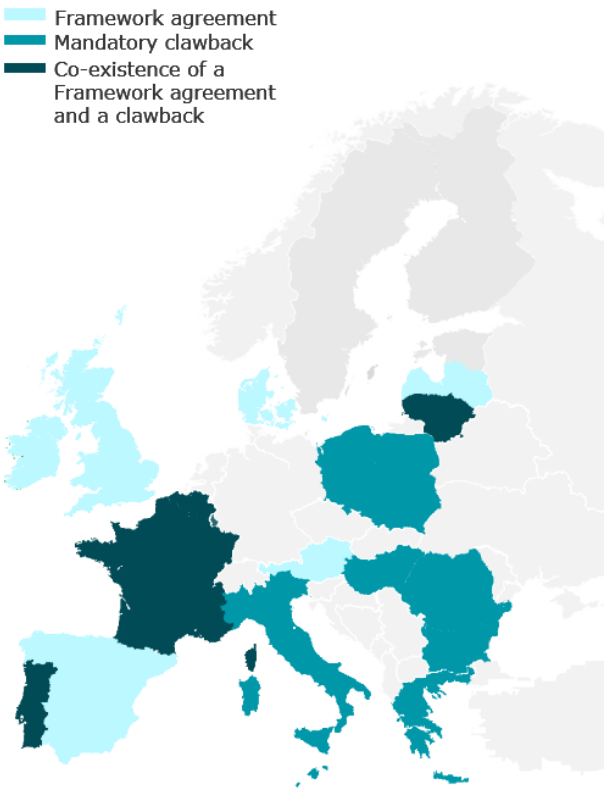
The Way Forward: *A Pact for Medicines*

In the recent years, similar plans have been materialized in many European countries through signing voluntary agreements between the government and the industry, based on mutual commitments from both parties.

Memorandums of Understanding

MoUs around Europe are voluntary agreements actualized between the government and the industry for a **timeframe of 2 to 5 years**, establishing **mutual commitments** from both parties. The nature of the commitments, which can be binding or non-binding, as well as the scope of the agreement can be significantly different from country to country, but the common purpose of all agreements is to enable a stable and predictable environment for the industry to operate and for the patients to have timely access to medicines.

Examples of typical Government commitments may include cost-containing measures, access for new medicines, expansion of coverage or enhancement of clinical development environment. From the Industry side, commitments can be financial or non-financial, with financial ones mostly revolving around rebates, clawback, pricing and improvement of off-patent competition, while indicative non-financial commitments can be guaranteed supply, clinical development, investment/employment, anti-counterfeiting and assistance with rational use schemes and value measurement.



Dimensions of MoUs

There are five dimensions across which the agreements can vary:

Governance

Nature of commitment (binding, non-binding, voluntary), duration, existence of legal obligations, signatories and scope

Budget

Caps on pharmaceutical expenditure, profit or price, clawbacks, rebates, realignment of prices, off-patent competition, horizon scanning tools, other saving measures

Market access

Rules for pricing and reimbursement, market monitoring, measures for the improvement of accessibility and availability of medicines

New payment models

New pricing models based on Real World Evidence (RWE) and outcomes data: Pay for Performance type contracts, risk-sharing conventions, Flexible pricing, Patient Access Schemes

Innovation

Increased predictability and legal certainty, enhancement of attractiveness for fiscal environment, reinforcement of clinical trials, establishment of minimum price for innovative products

Most MoUs represent binding commitments between the industry and government and in many cases (for example: in the UK) these are consecutively followed by renewed commitments. The level of detail and the obligations resulting from the agreements vary, but they all share the purpose of promoting sustainability in the market and predictability in the management of pharmaceuticals.

Country	Type	Description
 **2015-2018**		The industry pays contributions to the domestic health insurance in exchange for no other government's restriction. Part of the amount paid is dedicated to joint healthcare projects in the field of child health and prevention
 **2015-2018**		This "declaration of intention" includes a cap on pharmaceutical expenditure (made compulsory through a decree) and a description of measures aiming to improve access to innovative medicines and the attractiveness of the R&D environment
 **2016-2018(1)** **2016-2019(2)**		The two agreements regulate the price cap on reimbursable prescription medicines (1) and hospital medicines (2)
 **2016-2018**		The agreement regulates the pricing of reimbursable products and allows for companies which sign a convention with the European Committee for Health Products to reduce the Mandatory clawback set in the Law (LFSS)
 **2016-2017**		The agreement foresees industry compensations in case pharmaceutical expenditure's growth exceeds the pre-defined targets and safeguards access of patients to innovations through the use of common indicators
 **2016-2020**		The agreement describes the long-term cooperation between the industry and the government and defines rules on price regulation, including rebates and discounts for both retail and hospital medicines
 **2014-2016**		The agreement seeks to increase stability and predictability in the management of pharmaceuticals

Type of Agreement: **Binding** **Non-Binding**

Please refer to the Appendix on more detail on the Industry's and the Government's responsibilities assumed in each country

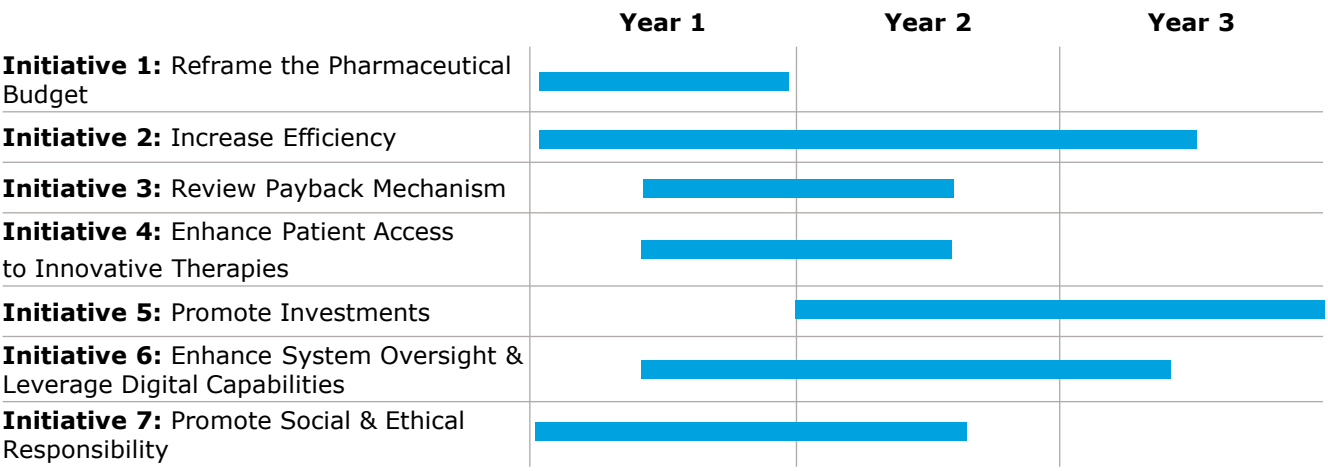
The Way Forward: *A Pact for Medicines in Greece*

The outlined initiatives can be used as the basis for materializing an agreement between the State and the Pharmaceutical Industry in Greece. The agreement should include a specific roadmap for the implementation of the initiatives.

An indicative roadmap for implementation, over a three-year period, has been developed by taking into account the following factors:

- **The anticipated outcomes of the various initiatives.** Initiatives that aim to address immediate needs have been prioritized over initiatives that are targeted towards increasing the efficiency of the system, in order to enable results in the short-term. The implementation of Initiative 7 has been also prioritized, to showcase the industry's commitment towards achieving the targeted vision.
- **The limited availability of resources.** Understanding that although all initiatives are contributing towards sustainability, their implementation cannot be executed in parallel due to the limited availability of resources, both human and financial.
- **The expected implementation time of the initiatives.** Initiatives that are expected to be implemented over a longer period of time have been move forward in order to allow sufficient time for their actualization.

Proposed Timeline



Conclusion

Conclusion: *Key Success Factors*

A successful shift towards a Sustainable and Patient Centered Pharma Policy, may be enabled by identifying the key areas for achieving the expected outcomes and ensuring alignment between the various stakeholders.

The outlined **future Vision** for Greece's Pharmaceutical policy aims to act as a tool for the creation of a **sustainable plan** between the Industry and the Government. This plan will support **value enhancement** throughout the health care value chain. It also represents the **long term ambition** for a pharmaceutical industrial strategy aligned with government priorities.

As such, the ***Vision*** for a Sustainable and Patient Centered Pharma Policy is designed with a view on achieving specific outcomes by enabling the **successful implementation** of the outlined initiatives.

In order for the Vision outcomes to be achieved and for the **initiatives to be successfully implemented,** it is necessary to ensure consent, among stakeholders, on the key principles of the proposed plan and on the pillars on which the initiatives were designed to form a coherent **medium term plan** which highlights **"The Way Forward"**.

Key Principles

01 **Build a Sustainable Budget**

02 **Share the Responsibility**

03 **Ensure Transparency**

The Way Forward

Reframe the pharmaceutical budget and increase the efficiency of the system to ensure sustainable financing and achieve controlled growth

Gradual rationalization and alignment with EU averages in terms of budget allocation

Introduce initiatives aiming to re-build the foundations of the ecosystem and act as safety nets to ensure sustainability over time

Conclusion: *Creating Value*

A Sustainable and Patient Centered Pharma Policy, has the potential to create value for all stakeholders involved in the health care value chain: the State, the industry, physicians and, most importantly, patients.

Patients are impacted positively by a pharma policy that sets them in the center by:

- **Ensuring universal access** to the healthcare system for all the population, including the uninsured population
- **Covering** more effectively their **unmet medical needs**
- **Monitoring** better their **health status** through personalized integrated electronic health records
- Gaining **timely and prioritized access** to life-changing innovations that will improve health outcomes

The State can capture value from the review of the pharma policy via:

- **Providing wider & better coverage** to the population.
- Enabling significant ***opportunities*** for development and growth through investments in the healthcare sector.
- ***Containing*** excessive demand and ***rationalizing*** costs in the entire health value chain
- Improving ***ethical practices*** and social responsibility
- Improving the ***competitive position*** of Greece in Life Sciences
- *Improve* ***fiscal performance,*** through achieving better business results, creating jobs and having a predictable market plan

The Industry can secure significant benefits and have the opportunity to grow by:

- Operating in a ***stable environment***
- Collaborating with the MoH in the collection and evaluation of RWE and clinical trial data for the purpose of ***optimizing*** product outcomes
- A simplified and ***streamlined system*** for market access, including faster and more ***integrated*** decision-making, ***transparent*** procedures and the opportunity for engagement with decision-makers
- Having access to a ***strengthened*** healthcare network which can ***facilitate*** evidence-collection and the ***adoption of innovation***

Physicians gain significant benefits via:

- ***Monitoring*** more efficiently their patients' ***outcomes*** through better data collection and integration
- Working in a ***flexible and empowered health system*** that acts collaboratively to adopt the best new offerings for its patients
- ***Contributing*** in world-class R&D evidence of a product's performance in real-world settings
- Receiving ***incentives that align*** with the promotion of the system's sustainability
- Taking advantage of breakthrough ***digital technologies***

Appendix I – MoUs In Europe

MoUs in Europe

The level of detail and the legal obligations resulting from the agreements vary, but they all share the purpose of promoting sustainability in the market and predictability in the management of pharmaceuticals.

Country	Industry Actions	Government Actions
	• Payment of voluntary contributions to domestic health insurance from pharma companies and wholesalers (125M euros in 2016 and up to 160M in 2017-2018)	• Government in exchange will respect the Pharma Master Agreement and will not impose further cost containment measures
	• Payback if expenditure is above cap (max clawback is 2,5% of the annual drug budget • Limiting of the medicine shortages • Improvement of competition in off-patent market	• Improvement of access to medicines: shorten reimbursement procedures, limit co-payment of patients, monitor access to new medicines • Favor a more competitive environment for the pharmaceutical industry (reduction of taxes, new law for the facilitation of clinical trials)
	• Price cap on both reimbursable prescription and hospital only medicines	• Maintain freedom of pricing • For reimbursable prescription medicines pricing is not regulated by ERP systems • For hospital medicines price cap is based on ERP and calculated as the average of prices in comparable countries
	• Mandatory clawback is set by Law (LFSS). It can be reduced if companies sign a convention with CEPS • Information to CEPS on medicine sales, volumes and prices, off label use and future innovative medicines with significant budget impact	• Accelerated procedure to set the price of most innovative products • Guarantee that the price of most innovative products will not be inferior to the lowest prices in Germany, UK, Italy and Spain • Setting up a steering committee to deal with any drug regulation issues and to calculate the savings due to medicines (e.g. savings on hospital expenditures)
	• Compensation is foreseen if expenditure growth is above the pre0defined targets • Non monetary compensations if expenditure growth is above Cap 1 • Payback if expenditure growth is above Cap 2	• Jointly monitoring with Farmaindustria of patient access to innovations with equity through the use of common indicators • Increased predictability and legal certainty for the pharma industry

Country	Industry Actions	Government Actions
	• Payback if growth percentage is above cap	• Maintain freedom of pricing at launch for branded medicines • No price cut • Facilitate Patient Access Schemes • Improve uptake of cost effective products • Provides legal certainty to pharma companies in comparison with statutory scheme which can be revised at any time and impose straight list price cut
	• Annual downward realignment of price (average of the relevant price in the 14 countries used for ERP) • Maximum proposed price for new medicines (inpatient and outpatient) based on ERP • Rebates on price of exclusive medicines • Provide information on drugs seeking P&R in coming years • Reduction of the price of LoE biologics and LoE small molecules	• Commitment to "secure timely access to innovative medicines offering enhanced health outcomes" • Increased predictability and legal certainty for the pharmaceutical companies
	• Reduction of the price of single-source off-patent medicines included in a list agreed by both parties • Avoid supply shortages • Ethical and transparent business practice	• Although non binding, the agreement includes clauses to improve the management of the reimbursement budget, improve access to patented medicines, innovation, develop ethical and transparent business practice etc. • The agreement should also avoid further cost containment measures

Appendix II – Good Practices

Good Practices: *Rationalize Demand*

Rationalization of the demand can be achieved through **vertical integration**, rational generics policy, incentivizing better prescribing behaviors and full implementation of enablers such as **patient registries** and **clinical protocols**.

Good Practice	Country	Description
Prescribing Behaviors & Incentives		The **TARGET Antibiotics Toolkit** influences prescribers' and patients' personal attitudes to responsible antibiotic prescribing. Interventions can be implemented on short term basis (enhanced feedback, improved leaflet), mid term basis (substitution of antibiotic therapy, reducing patient appointments, monitoring GP decision making) and long term basis (making antibiotic packaging salient, presenting resistance as a social threat)
		Provision of incentives for GPs to prescribe through pay for performance scheme. Pay for performance led to health savings by increasing screening and prevention, reducing the prescription volumes of some medications such as antibiotics and encouraging the prescription of generic medications
Patient Registries		Extensive national system of online registries support the country's managed entry strategy. These begun in 2005 and include: (a) drug production monitoring registries, (b) therapeutic indication monitoring registries and (c) therapeutic plan registries.
Clinical Protocols		The use of evidence-based clinical protocols, developed by HAS, is not mandatory and financial incentives schemes are provided, such as the introduction of a pay-for-performance model which complements the prevailing fee-for-service physician remuneration
Generics & Biosimilars Policy		**National Action Plan for the promotion of Generics and mandatory INN prescribing**. The plan will introduce national goals and aims to remove any remaining obstacles to the use of generics in France. It includes a national advertising campaign for the general public and health professionals and rules for patients to pay our of pocket if they prefer not to select the generic medicine from the pharmacist.
		**Price controls and promotion of generics** were introduced and increased generics market share by volume from less than 40% in 2007 to over 60% in 2015.
		**Competition among generics** is encouraged and insurers only reimburse the cheapest generic. The penetration of generics 24 months post-patent expiry is the highest in Netherlands (62%) among EU countries.
		Physicians (GPs and specialists) and dentists are required to prescribe a certain minimum percentage of low cost drugs, the so-called **"quotas"** since 2006. biosimilars are also included and the GPs are encouraged to prescribe at least 20% for treatment-naïve patients
		**Accelerated market entry** for Generics and **mandatory pharmacy substitution** with the cheapest generic since 2006. by 2016, generics market share increased from 14% to 47.5%
Vertical Integration		Royal Wolverhampton Trust created a new directorate to link GPs and secondary care services, in a mutually sought collaboration between primary care and acute sectors. This led to an increase in appointment availability and facilitated communication between providers when managing complex patients.

Good Practices: *Rationalize Supply*

Rationalization of the supply side can be achieved through pricing and reimbursement policies, efficient & transparent HTA process, transparent, predictable and fair rebate & clawback mechanism, introduction of MEAs and effective hospital tendering.

What can we learn from other countries' experience:

Good Practice	Country	Description
HTA		A key issue in the HTA assessment process across Europe is transparency. This is the case in England, Poland, Germany, Netherlands and France. Without transparency and consultation, HTA is likely to miss key information that could be provided by stakeholders: industry, patients and healthcare professionals
MEAs		Financially based MEAs, including include (a) Cost sharing and (b) Capping. Cost sharing represents a discount on the cost of the first cycle of treatment, or the entire course of therapy, for all eligible patients. This type of deal is generally used in cases of uncertainty regarding the potential financial impact of a new medicine. Capping sets ceiling on expenditure on a drug per patient, beyond which the manufacturer covers all remaining costs. The MEAs delivered significant savings that reached €531.8m in 2017.
		Performance based agreements applied to drugs that are given an improvement in actual benefit rating of V (i.e., no improvement), but for which the manufacturer claims a clear advantage over established treatments that can only be proven in the real world. Manufacturers may be required to conduct real-world studies or to monitor outcomes in individual patients, possibly by means of a registry. The CEPS reports that, in 2017, MEAs saved the French healthcare system €1.365 billion, an increase of 197% in just five years.
Data Warehouse		Establishment of the Heath Data Hub in 2015 – a health data agency charged with developing a new system that would aggregate healthcare data, make it open and available to the appropriate parties — hospitals, researchers, physicians and patients — and provide a platform that encourages data analysis and the creation of new applications based on that data.

Good Practices: *Effective & Fair System Oversight*

The system oversight can be enhanced through the introduction of an independent **HTA organization,** introduction of the reciprocity principle for **clawback & rebate** and leveraging the role of the **spending monitoring committee**.

What can we learn from other countries' experience:

Good Practice	Country	Description
Clawback & Rebate		Clawback imposed on generics, while innovative medicines are financed through MEAs.
HTA Organization		HTA organizations that can take decisions independently, as arms' length bodies, such as HAS or NICE, has been proved to have reduced bias.
Partnership Working		Established the National E-Health Portal, to: (a) Enable web access to Electronic Patient Records (EPR) via central document indices to data kept in the individual hospitals and General Practitioners' (GP) offices, (b) Provide a portal for electronic communication between citizens and healthcare professionals (e.g., e-referrals, e-prescription) and (c) Allow patients, their families, and healthcare professionals access to up-to-date information. The partnership led to increased system integration, reduction in various transaction costs and benefits in national, practitioner and patient level.
Co-Responsibility		Industry and the MoH signed an MoU in May 2019 based on which they co-contribute both to the clawback payments. Financing is based on last year's expenditure and the ministry accepts the responsibility to enforce the cost containment measures; this leads to the understanding of the co-responsibility notion.

(1) IOVE

Good Practices: *Promote Innovation*

Innovation can be promoted through a policy framework that incentivizes growth and investments in clinical trials, protection of the innovation funding, establishment of horizon scanning process, accelerated access framework, system interoperability & integration and leveraging partnerships to increase economies of scale & skills.

What can we learn from other countries' experience:

Good Practice	Country	Description
Incentives for Clinical Trials		The innovation deduction made Belgium an attractive location for conducting R&D and IP activities. This deduction is an incentive which provides for a deduction of 85% of the qualifying net IP income, effectively reducing the related maximum effective tax rate to 4,4 % (in 2018-19) / 3,8 % (as of 2020). The innovation deduction is applicable to Belgian companies as well as foreign companies having a permanent establishment in Belgium, irrespective of their size or industry.
Innovation Funding		For life-threatening or rare diseases, an intervention from a 'Special Solidarity Fund' (a public fund) can be asked for products that are not (yet) covered by basic health insurance. The Fund, is an integral part of mandatory basic health insurance, explicitly stipulates that patients first have to seek reimbursement for a new technique from their voluntary additional health insurance before they can file a request.
Horizon Scanning		Supranational Horizon Scanning Collaborations (Valetta, BeNeLuxA). The International Horizon Scanning Initiative, supported by the broader BeNeLuxA, aims to build a permanent horizon scanning system that can support countries and institutions in policy planning and their decision making regarding the reimbursement of new pharmaceuticals. It includes (a) all medicines in development from early Phase I, (b) a filtered list of originator drugs in Phase II, III, IV and (c) High impact technologies including details of failed or withdrawn products.
Accelerated Access Framework		The Accelerated Access Review aimed to speed up access to innovative drugs, devices and diagnostics for NHS patients. It focuses on affordable medicines or technologies which can dramatically improve efficiency, fill an unmet need or make a step-change in patient outcomes. The scheme aims to be cost-neutral to the NHS, with technologies that cost the NHS money balanced by those that offer substantial efficiency savings.
Real World Evidence Capacity Building		SNIIRAM National Claims Database provides no access to data for pharma and merges anonymous information of reimbursed claims from all these plans, linked to the national hospital-discharge summaries database system (PMSI) and the national death registry.
		The CPRD database is one of the largest primary care databases in the world, providing anonymized UK EHRs to researchers within academic, regulatory, and pharmaceutical organizations. Pharma companies have access to 80% of raw data.

Deloitte.

Follow **Deloitte Greece** on: