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HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

The Way Forward: A Roadmap for Greece's Pharmaceutical Policy

November 2025

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List of Abbreviations

AI	Artifical Intelligence
AIFA	Italian Medicines Agency
API	Active Pharmaceutical Ingredient
ASMR	Improvement of medical benefit
ATC	Anatomical Therapeutical Chemical
ATMP	Advabced Therapy Medicinal Product
BI	Business Intelligence
BoD	Board of Directors
CAR	Chimeric Antigen Receptors
CEB	Council of Europe Development Bank
CMA	Critical Medicines Act
CoE	Center of Excellence
CT	Computed Tomography
CVD	Cardiovascular Disease
DDD	Defined Daily Dose
DRG	Diagnosis Related Groups
DTC	Daily Treatment Cost
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industry Associations
EHDS	European Health Data Space
EHR	Electronic Health Record
EIB	European Investment Bank
EKAPY	National Central Health Supply Authority
EOPYY	National Organization for the Provision of Health Services
ERP	External Reference Pricing
ESF+	European Social Fund Plus
FIT	Fecal Immunochemical Test
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GP	General Practitioner
GS	General Secretary
GVA	Gross Value Added
Gx	Generic Medicine
HAS	French National Authority for Health
HCP	Healthcare Practitioner
HDPA	Health Data Permit Authority
HERA	Health Emergency Preparedness and Response Authority
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health Maintenance Organization
HMVO	Hellenic Medicine Verification Organization
HPV	Human Papillomavirus
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
ID	Identification
IDIKA	e-Government Center for Social Security
IFET	Institute of Pharmaceutical Research and Technology
IOVE	Foundation for Econonmic and Industrial Research
INN	International Non-proprietary Name
ISO	International Organization for Standardization

List of Abbreviations

IT	Information Technology
JCA	Joint Clinical Assessment
KMES	Center for Computerized Prescription Processing
KPI	Key Performance Indicator
LfL	Life for Like
MAH	Marketing Authorization Holder
MEA	Managed Entry Agreement
MIP	Macroeconomic Imbalance Procedure
MoH	Ministry of Health
MoU	Memorandum of Understanding
NC	Negotiation Committee
NCD	Noncommunicable Disease
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NUB	New Examination and Treatment Methods
PAC	Patient Advisory Council
PEDY	National Primary Health Care Network
PHU	Primary Health Unit
PICO	Population, Intervention, Comprison, Outcome
PKU	Phenylketonuria
PoV	Point of View
R&D	Research & Development
RRF	Recovery and Resilience Fund
RWD	Real World Data
RWE	Real World Evidence
Rx	Prescription
SFEE	National Pharmaceutical Industry Association
SGP	Stability and Growth Pact
SME	Small and Medium-Size Enterprise
SMR	Medical Benefit
SSN	Social Security Number
VAT	Value-Added Tax
VPN	Virtual Private Network
YoY	Year over Year

Methodology

This report is the product of a highly iterative and inclusive process that aimed to capture and address all key challenges in a comprehensive manner

Methodology Overview

The reform plan was developed through **a structured and inclusive process**, combining rigorous system analysis, extensive stakeholder engagement, and targeted international benchmarking.

Input was gathered from the industry through **structured interviews, surveys and ongoing collaboration with members of SFEE**. In parallel, consultations were held with **key actors across the pharmaceutical ecosystem**, including public authorities, healthcare practitioners and patient representatives, to ensure the proposals reflect **shared priorities** and **real-world constraints**.

Best practices from comparable EU countries were reviewed, offering **tested examples of effective policy tools**, while as-is analysis provided a robust understanding of the **Greek system's current state and institutional limitations**.

All insights were synthesized through a **series of iterative workshops,** which served to challenge, refine and validate the resulting recommendations.

The final proposals were carefully tailored to **support open dialogue, informed decision-making and practical implementation** by all stakeholders, both within and beyond the public sector.

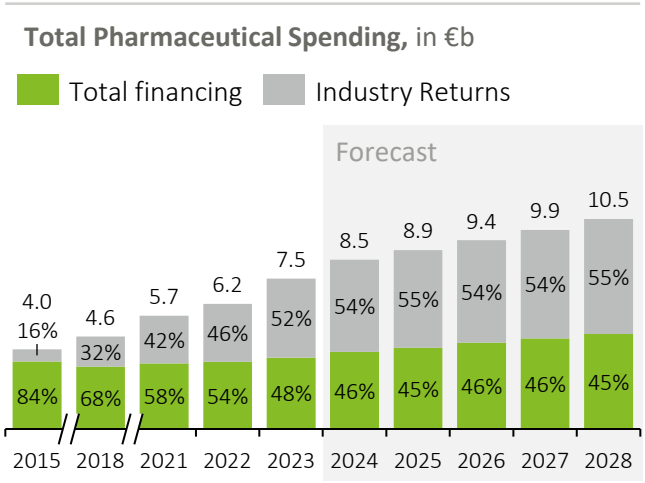
Note: [1]SFEE executives and representatives of 7 SFEE members (incl. both local affiliates of multinational organizations and Greek companies)

Executive Summary

Executive Summary

This report aspires to provide a **comprehensive roadmap for the transformation of Greece's pharmaceutical system**, aiming to improve sustainability, ensure equitable access, and align with international standards. Through a **data-driven methodology** and **broad stakeholder engagement**, the study **identifies the key structural challenges**, **evaluates the current policy framework** and **proposes a series of pragmatic, impactful reforms to ensure long-term resilience.**

The Greek pharmaceutical policy landscape is currently defined by **fragmentation, inefficiencies and persistent fiscal pressure**. Despite relatively low nominal prices and a notable increase in public spending, **industry returns remain the highest in Europe**. These imbalances are compounded by the absence of strategic demand management, weak



coordination between separate budget channels, inadequate monitoring of prescribing behavior, and a chronic underutilization of real-world data. As a result, **resources are often misallocated,** and **the system struggles to shift toward a value-based, sustainable model of care.**

To address these challenges, **a structured strategy development process was undertaken**, integrating analytical insights, national priorities and feedback from key public and private sector stakeholders. The process began by **establishing a shared strategic direction rooted in foundational principles**, namely,

(*) Interviews with pharma ecosystem stakeholders

collaboration, data-driven planning and decision-making, and long-term value for both patients and the healthcare system.

Central to this effort was the **agreement on an overarching theme** that serves the vision: **building trust while fostering the business environment with the goal of ensuring access**. This theme is a guide for identifying inefficiencies and potential improvements that could be implemented **without compromising patient access or undermining incentives for investment and innovation**. In parallel, a clear performance ambition was set by **defining what "good" looks like for the Greek pharmaceutical system** drawing on international best practices, credible baselines and transparent evaluation criteria.

Crucially, alignment was achieved between the public and private sector on the **importance of setting clear targets** and **embracing shared accountability** for future system performance. This joint commitment includes the creation of **mechanisms to track progress**, review results regularly and ensure **collaborative implementation** of reforms. Building on this consensus, the **target for public spending in 2028 is €4.5b**, with incremental increases above current commitments to match total spending's growth rate. This approach, along with a goal for reducing total spending backed by **targeted initiatives**, aim to **gradually achieve ~40% industry returns by 2028.**

Executive Summary

To support long-term sustainability, improve patient outcomes, and increase predictability for all actors, the suggested reforms are structured around three strategic areas. Each area addresses a specific set of systemic weaknesses and includes focused proposals that are **actionable, measurable**, and **aligned with international best practices**. Together, they provide a coherent roadmap for reform implementation.

Bridging the Financing Gap

These reforms aim to correct the chronic mismatch between healthcare needs and available public funding by improving system efficiency and financial governance.

- **Manage demand holistically**: Consolidate fragmented budget lines, rationalize closed sub-budgets, strengthen prescription controls, enforce adherence to clinical protocols, and introduce accountability mechanisms to ensure resources are directed where most needed.
- **Secure adequate financing**: Address systemic budget overflows, such as protection mechanisms or uninsured populations, introduce a dedicated innovation fund.
- **Unlock data potential**: Enhance the accessibility, quality and interoperability of health data to support real-time monitoring, predictive planning, and collaborative decision-making with all stakeholders, including industry.

Transforming the System

Focused on strengthening structural enablers, improving transparency, and embedding value-based principles into the core of pharmaceutical governance.

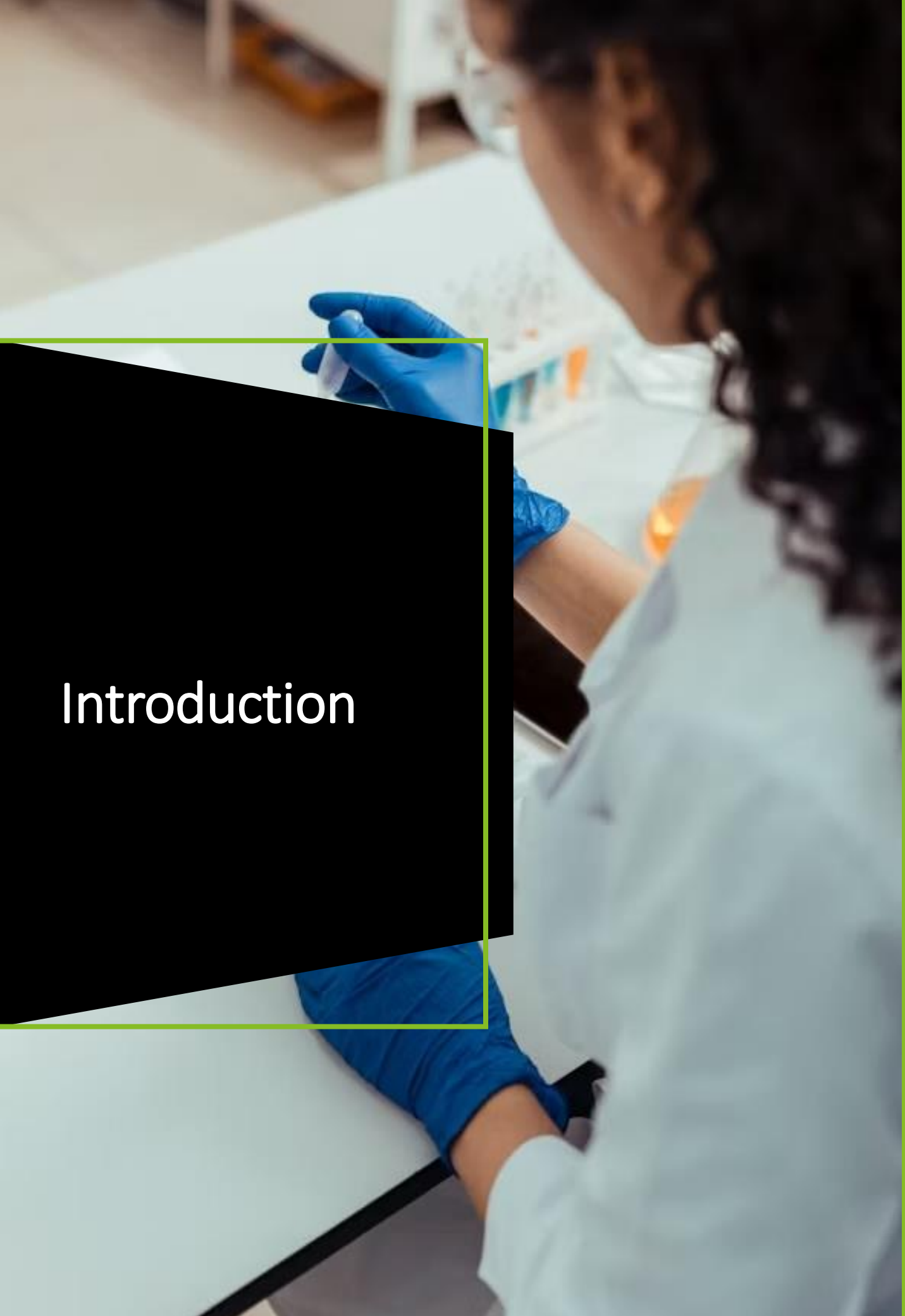
- **Enable data ecosystem**: Build a cohesive governance model for health data, enabling secure sharing, structured access and policy-relevant analytics.
- **Introduce national pharma council**: Create a multi-stakeholder governance body to coordinate policy direction, support investment planning, and institutionalize long-term collaboration between state and industry.
- **Reform HTA**: Align national processes with upcoming EU regulation while improving evaluation capacity, transparency, and role clarity in the market access process.
- **Promote value-based negotiations**: Strengthen the link between pricing and outcomes, using real-world data and risk-sharing mechanisms to guide reimbursement levels.
- **Rethink reimbursement framework**: A collaborative project aimed at redesigning rationale, diving into core principles such as positive list inclusion criteria and value-based reimbursement scales

Broadening the Perspective

To recognize the importance of investing upstream—before high system costs occur—by focusing on population health management and preventive care.

- **Strengthening primary care**: Reinforce the role of primary care in disease management, improve care coordination, and reduce reliance on hospital-based treatments.
- **Ramping up prevention focus**: Expand early detection and screening programs, incorporating risk-based outreach and digital tools to support proactive and cost-effective health interventions.

The proposed reforms should be viewed as a **cohesive set of mutually reinforcing actions**. The combined implementation is essential to achieve meaningful change in the system's sustainability, access and efficiency. A key enabler of this roadmap is the principle of reciprocity with the **industry being a strategic partner** that supports the state towards the common goal.



Introduction

Value of the Pharma Industry

Investment in pharma innovation drives efficiencies across the health ecosystem, improves quality of life and supports economic growth and resilience

The pharmaceutical industry is a cornerstone of any resilient healthcare system. The value of medicines goes far beyond treating illness; they improve lives, strengthen public health, and support economic resilience and growth. Innovation acts as a driving force across these dimensions, enabling sustainable, long-term impact.

Key Value Drivers

Patient Perspective

Quality of Life: Medicines can significantly enhance a patient's daily functioning and overall well-being, especially for those living with chronic or severe illnesses.

Availability of Alternatives: The presence of multiple treatment options empowers patients and clinicians to select the most appropriate therapy, supporting personalized care.

Public Health Perspective

Disease Prevalence and Incidence: Pharmaceuticals contribute to reducing the spread and impact of diseases across populations, particularly through prevention and control.

Clinical Endpoints: The value of a medicine is also measured by its impact on survival rates, disease progression, or remission — demonstrating its clinical effectiveness and real-world outcomes.

Socioeconomic Perspective

Cost Considerations: While some treatments may have a higher upfront cost, they can help avoid downstream expenses by reducing hospitalizations, complications, the need for invasive procedures, and time to recovery.

Productivity Impact: Effective treatments help individuals return to work, reduce absenteeism, and support workforce participation; boosting overall economic productivity.

Innovation as an Enabler

Innovation amplifies value across all areas. It accelerates the development of breakthrough therapies, expands treatment possibilities, and reshapes the standard of care. From precision medicine to advanced biologics, innovation ensures the continuous evolution and sustainability of the healthcare ecosystem.

21% Reduction in cancer mortality rates since 1991

23% Decrease in risk of death or hospitalization for diabetes (II)

33% Of increase in life expectancy due to new medicines replacing older

Source: EFPIA, PubMed

Greek Pharma Industry

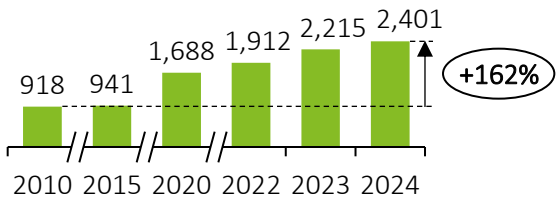
The industry's footprint in Greece is significant and multidimensional, generating value for the economy and society as a whole

The pharmaceutical industry in Greece plays a significant role in supporting the national economy, contributing to employment, industrial growth, and investment in clinical research. Its footprint is both substantial and multifaceted, as evidenced by most recently updated key indicators.

Economic Impact

The sector's **total GVA** to the Greek economy is **€6.9b, or about 3.1% of GDP**, highlighting its role as both a healthcare pillar and economic driver. For **every €1 of value added** by pharmaceutical firms, **the wider economy gains an extra €1.30**—showing strong ties to sectors like logistics and professional services. The sector also has a major fiscal impact, **generating ~€1.9b in tax revenue**, including corporate, payroll, and indirect taxes, showcasing its importance to public finances.

Figure 1. Pharmaceutical Production , in €m

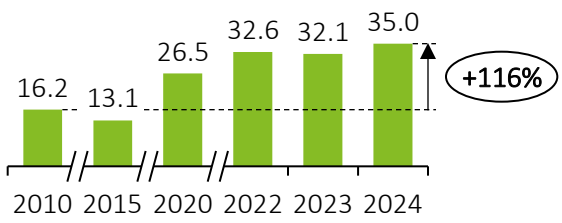


Source: SfEE, IOVE

Direct Employment Contribution

In terms of employment, the pharmaceutical sector supports a significant number of jobs, with a **total contribution of approximately 119,000 positions** (incl. direct, indirect and induced employment), representing **2.8% of total employment** in the country. In fact, **each job in the pharmaceutical industry supports an additional 2.4 jobs,** highlighting the sector's strategic role in creating stable, high-quality employment opportunities across various levels of specialization.

Figure 2. Direct Employees, 000'

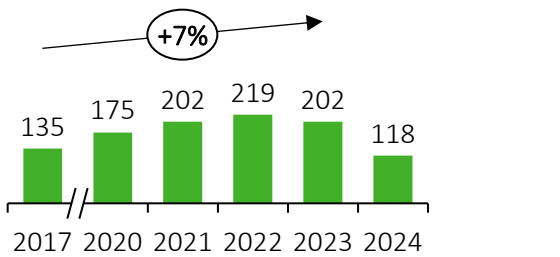


Source: SfEE, IOVE

Clinical Trial Ecosystem

Clinical trials in Greece were on an upward trend until 2022, with much room for improvement in clinical trials conduction through **investment incentives, regulatory simplification, and innovative trials adoption** such as in decentralized and cross-border clinical trials. Clinical trials are **necessary for Europe** to maintain its **competitiveness in the global pharmaceutical innovation landscape, improve patient access** to cutting-edge treatments, while they also contribute to local economies.

Figure 3. Clinical trials, abs



Source: SfEE, IOVE, EFPIA

Structural Inefficiencies

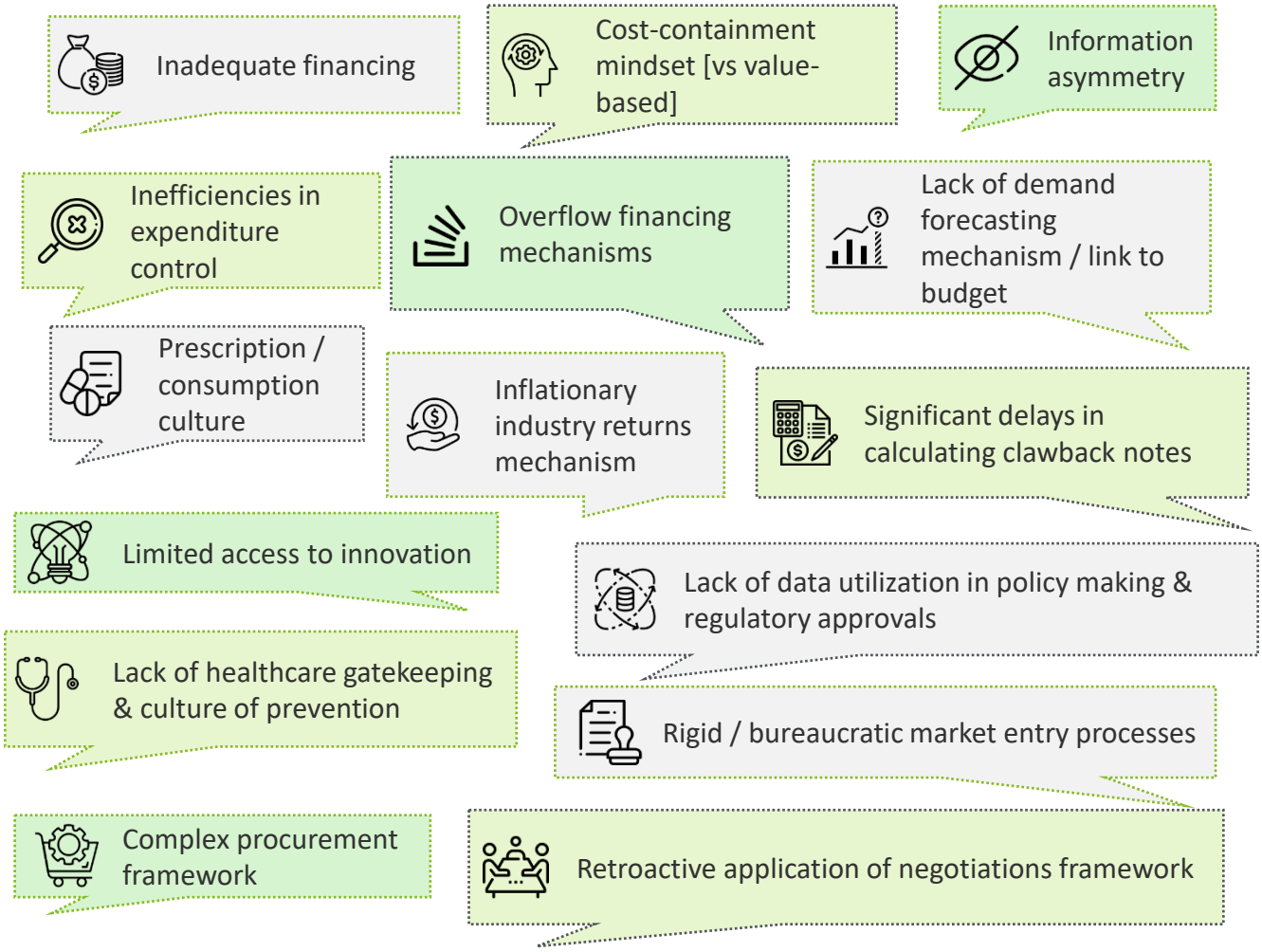
The Greek pharma system faces a set of entrenched structural weaknesses, which limit its capacity to function efficiently, adapt to change and deliver sustainable outcomes

Despite efforts to stabilize the system, embedded **inefficiencies** continue to limit its effectiveness and long-term sustainability. These challenges span across **policy design, funding mechanisms, administrative processes, and care delivery**, creating a fragmented and reactive environment that obstructs reforms and undermines trust.

Methodology

A structured survey was conducted among SfEE member companies to explore the industry's outlook on the current framework and its likely evolution in the coming years. The survey captured the industry's view on structural pharma system's inefficiencies.

Key Dimensions of Pharma System's Inefficiencies



Source: Primary research to SfEE members, n=24, Deloitte Analysis

Industry's Expectations

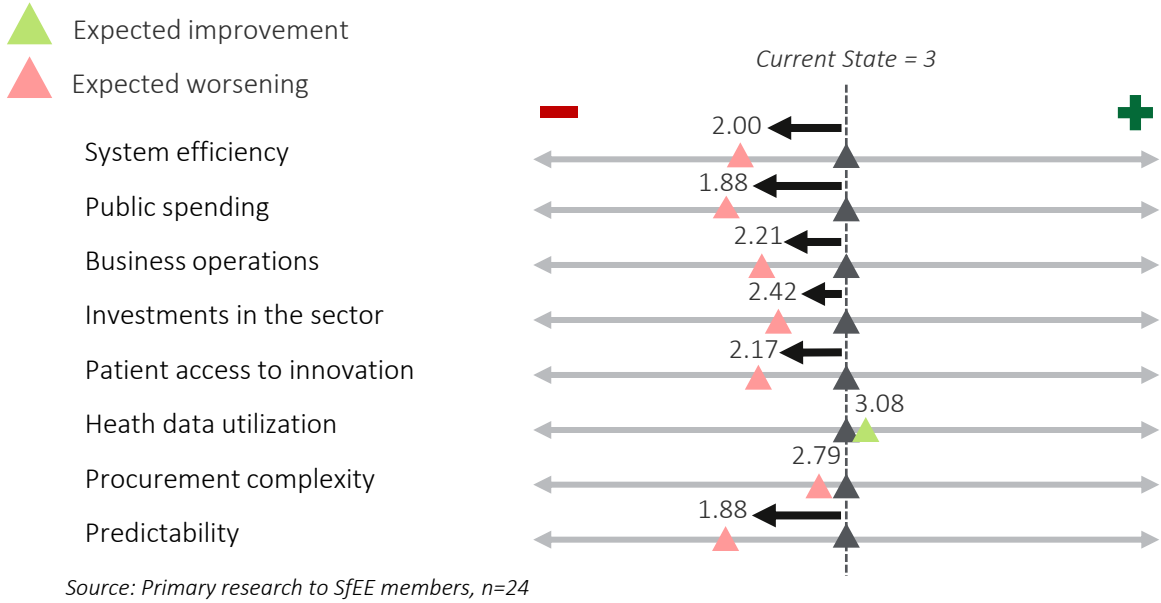
Industry expectations point to worsening performance across key areas, underlining the need for a more stable and investment-friendly policy environment

Industry's Point of View

Primary research among SfEE member companies highlights a **shared expectation of deterioration** across key areas of the pharmaceutical system over the next 3–5 years, if structural reforms are not implemented. Companies anticipate **worsening system efficiency, low predictability, limited access to innovation** and **slow health data integration**, reflecting persistent weaknesses. **Public spending and investment** prospects are also seen as unlikely to improve.

Figure 4. Industry Expectations, (input from primary research)

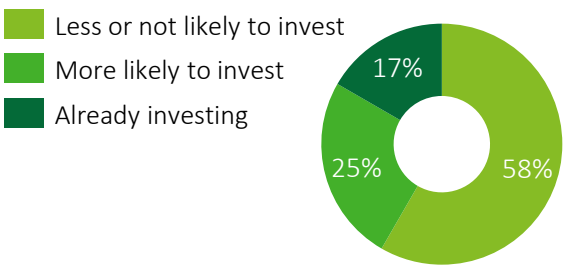
Assuming the existing framework persists, please assess the following dimensions over the next 3-5 years with a scale 1 – 5 (1 = Significantly worse situation vs today and 5 = Significantly better situation vs today)



Source: Primary research to SfEE members, n=24

Figure 5. Investment Appetite, (input from primary research)

How likely is your organization to make a significant investment (>€5m) in the Greek market?



Source: Primary research to SfEE members, n=24

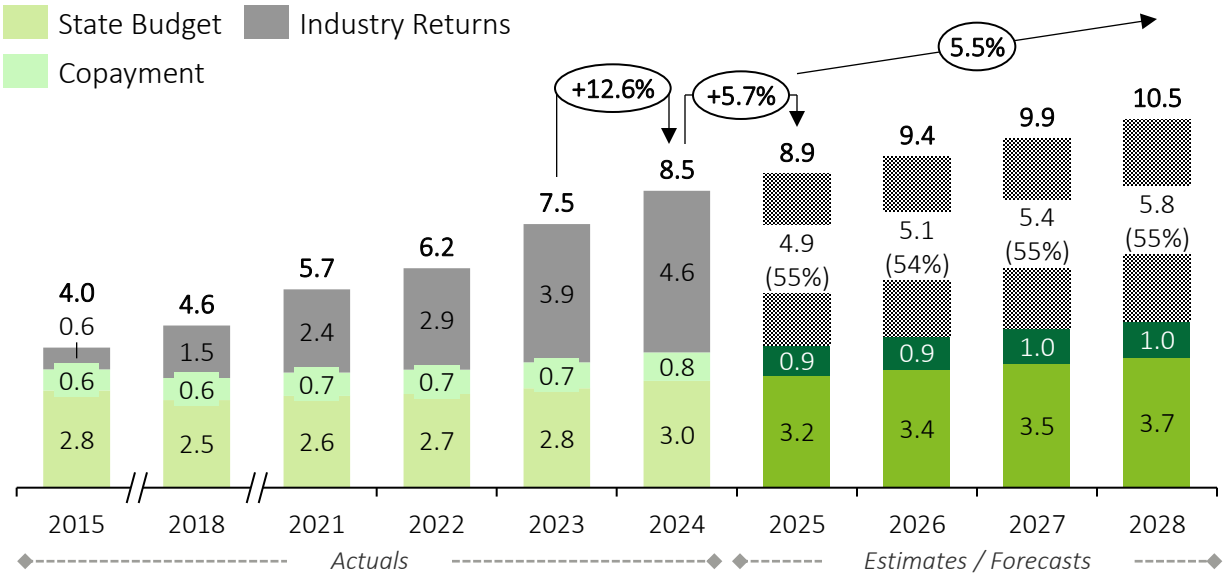
In parallel, the **investment outlook** remains notably cautious with a **majority of companies (58%)** reporting they are **less or not likely to invest** in the Greek market under the prevailing conditions. The main reasons cited were **regulatory uncertainty** & transparency, **excessive industry returns**, **slow administrative and legal processes** and uncompetitive incentives & lack of cooperation with the state.

A shift toward a more stable, transparent and **investment-friendly environment** is therefore seen as a pressing need, in order to safeguard patient access, innovation, and sectoral sustainability.

A Call to action

Rising pharmaceutical expenditure, largely absorbed by the industry, underscores the urgency for structural reforms to ensure long-term system sustainability

Figure 6. Reimbursable Pharmaceutical Spending Forecast, in €b



2023-2025 Assumptions, Forecast per Channel	
Retail & EOPYY Pharmacies	2023 & 2024 figures from IOVE
	2025 based on Q1 indications *Assumptions: Retail: 3.5% , EOPYY: 5.5%*
Hospital	2023 & 2024 figures from IOVE
	2025 from industry consensus *7.5% annually*

2026-2028 Spending, Forecast per Funding Source	
Reimbursable Spending	Based on IQVIA market report (5.5% annually)
Industry Returns	Balancing figure vs. total
Copayment	Fixed at average of % of total 2022-2025 (10%)
State Budget	€100m increase YoY through RRF + % change of GDP

Source: EOPYY, SfEE, Deloitte Analysis

Expenditure Growth

Crucially, total spending follows an increasing trend, while the **industry's contribution exceeded the state's for the first time in 2022**, a trend which is expected to continue through 2028. This outlook partially reflects the increased cost of innovative drugs entering the market, showcasing the need for more thoughtful and efficient allocation of resources.

The resulting imbalance reflects a **policy framework that responds to cost growth with short-term containment tools**, rather than long-term reform. Left unaddressed, this trajectory will place increasing pressure on all stakeholders, while limiting the system's capacity to deliver access and innovation.

Need for Coordinated Reform

The combination of structural inefficiencies and rising cost pressures highlights the need for **coordinated and forward-looking policy action**.

Without targeted reform, the system risks becoming **fiscally unsustainable and structurally inefficient**, limiting its ability to tackle waste and the value that can be gained from the **innovation momentum** in the coming years.

Social Dimension of Industry Returns in Greece

The current model in Greece that relies heavily on industry returns, drives higher costs, limits access, and erodes value across the healthcare system

The application of return mechanisms across the full continuum of care has led to distortions not only at the operational level but also in terms of patient access, health system performance and overall societal value.

Care areas where industry returns mechanism is implemented

Pharmaceutical returns 2023: ***€3.9b***

Healthcare providers returns 2023: ***~€0.8b***

Prevention

- Limited focus and financing towards prevention (despite recent steps towards that direction)

Outpatient Healthcare Services

- Increasing Out-of-Pocket expenditure
- Operational inefficiencies

Inpatient Healthcare Services

- Cost-cutting prioritization & operational inefficiencies
- Lower quality of care and patient satisfaction
- Increased costs from interventions that could be avoided

Pharmaceutical Products / Treatments

- Reduced health outcomes
- Delays in treatments / access to innovation
- Increased spending (inflationary mechanism)

Ambulatory Services

- Limited diagnostics capabilities & delayed diagnoses
- Lack of investments in technology

Impact on Patients

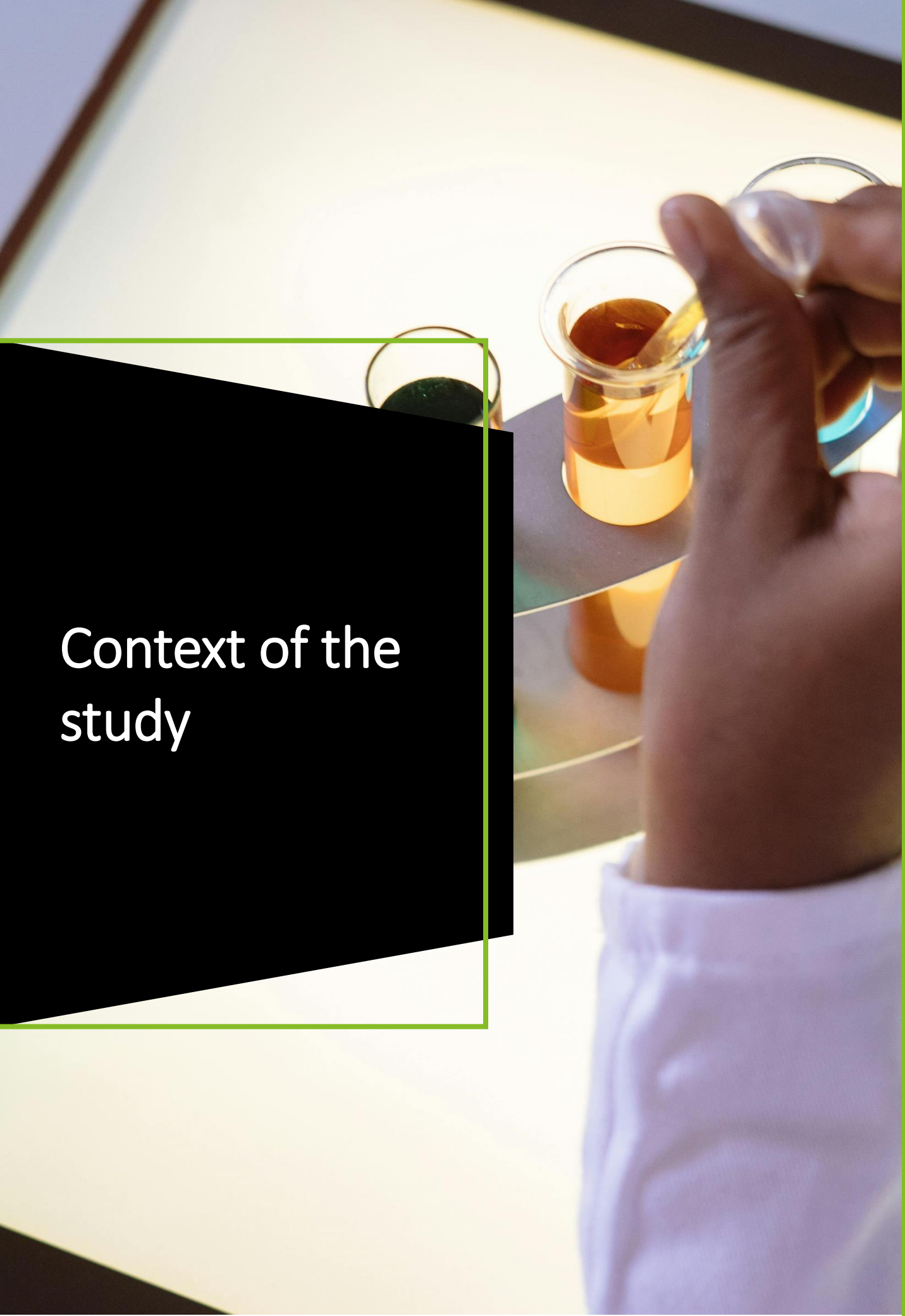
Restricted and **uneven access to innovative medicines**, as many products become available through alternative channels, or not at all, **enhancing inequalities** (especially for essential medicines).

Impact on Healthcare system

Discouragement of healthcare investments (across the value chain) due to a highly complex business environment. Simultaneous inability to draft **efficient pharmaceutical and broader healthcare policies.**

Impact on Healthcare system

Value erosion through the **loss of jobs**, income, profits and taxes (due to limited business activity in the sector) and increase of **total healthcare costs**, as part of the cost of **system's inefficiencies** is being transferred to the **patients / citizens.**



Context of the study

Pharmaceutical Market Drivers

As populations age and demand grows, the pharmaceutical sector innovates amid global competition and differing views on value

As populations age and the need for advanced therapies increases, the pharmaceutical sector is under growing pressure to sustain innovation. This happens in the context of global competition and differing perspectives on how the value of innovation should be assessed.

Market Landscape

Demographic Changes

Populations across Europe, including Greece, are clearly ageing. Life expectancy has increased significantly, now reaching an average of **81.5 years**, and the proportion of people over 65 continues to rise. In Greece, this group represents **23% of the population**, compared to **21% across the EU overall**. These demographic shifts are reshaping the demand for long-term pharmaceutical care, with implications for healthcare planning, workforce needs and public spending.

Chronic Disease Prevalence

Improved survival rates from once-deadly diseases, driven by innovative treatments, have contributed to the **growing prevalence of chronic conditions**. In Greece alone, **25% of the population** suffers from at least one chronic condition. This growing burden intensifies demand on healthcare infrastructure and elevates the need for innovative, long-term therapeutic options that improve quality of life and reduce system pressure.

Evolving Epidemiology

In Greece, **behavioral and lifestyle factors**, such as smoking, poor nutrition, and physical inactivity, are key drivers behind the **rising prevalence of NCDs**, including lung cancer, cardiovascular disease, and diabetes. These trends, together with an ageing population, are reshaping the country's epidemiological profile and **increasing demand for more personalized therapies** and innovative pharmaceutical solutions.

Innovation Pressure Points

Precision Treatments

Advancements in clinical trials and data-driven technologies have enabled the development of precision medicines. These therapies deliver **better health outcomes**, but they also bring **higher R&D and regulatory complexity**, requiring substantial investment and specialized infrastructure.

Complex Innovative Products

New treatment approaches like **CAR-T therapies and genome-based applications** are more effective but often **costlier and harder to manage**. Their production and delivery processes are complex, increasing the overall cost of care and raising challenges for widespread implementation.

Orphan Drugs Penetration

As equity becomes a core priority in healthcare, **expanding access to treatments for rare diseases gains urgency**. Orphan drugs address these needs but remain high-cost due to limited patient populations, despite **growing R&D activity** supported by technological and clinical advances.

Global Competition Dynamics

Maintaining a strong innovation base is critical in responding to evolving needs and long-term system sustainability. The **United States remains the global leader** in innovation, while **China is rapidly gaining ground** as a major biotech force. This landscape is placing **growing pressure on Europe** to preserve its competitiveness and sustain investment in R&D.

At the same time, **U.S. policy shifts,** such as the **"most-favored-nation" pricing model**, aim to reduce domestic costs by tying them to international prices. These changes may **alter global pricing structures** and **impact the economic viability** of innovation

Source: SfEE, IOVE

National Fiscal Landscape Overview

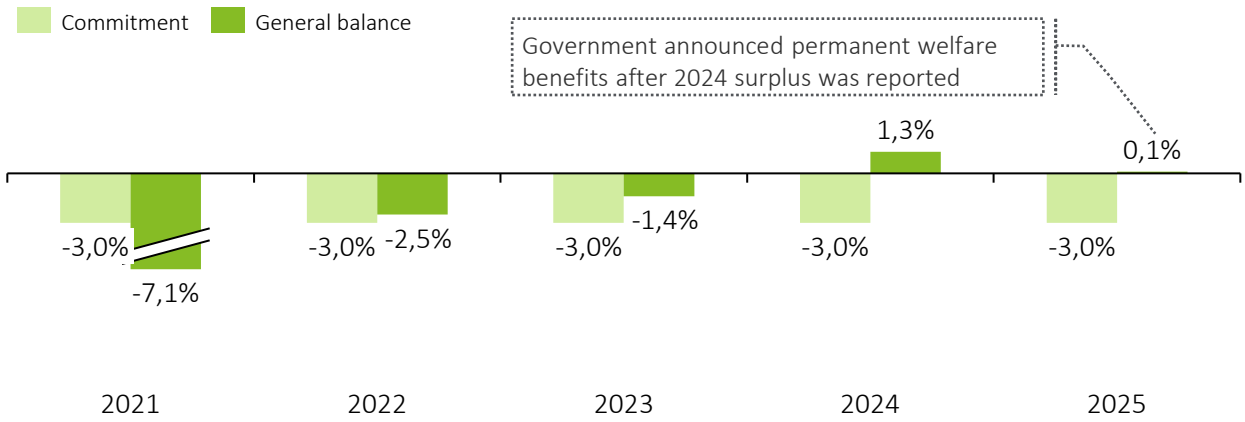
Greece has made significant strides in improving its fiscal and financial position, while current fiscal policy has prioritized welfare measures

Fiscal Framework Context

The current EU fiscal surveillance framework has been in effect since 2024, while commitments by member states were suspended under the General Escape Clause from the start of the pandemic until 2023. As shown in Figure 7, **Greece has overperformed its commitments** under the Stability and Growth Pact, being 1 of only 6 EU countries to **post a surplus in 2024**. This surplus created **available fiscal space for the state to reinvest** according to national priorities. A share of this fiscal space should be allocated to **strengthen the pharmaceutical framework**, either through increased spending or financing targeted reforms, to **enhance system alignment with strategic health objectives** and evolving EU-level standards. Notably, the latest welfare measures were announced on a permanent basis after the 2024 surplus (net of interest) was confirmed in April 2025.

Source: European Commission, Ministry of Economy and Finance

Figure 7. General Government Balance, % of GDP



Source: Ministry of Economy and Finance

Table 1. EU Fiscal Framework Highlights

Stability and growth pact	The main budgetary planning and policy coordination framework. The SGP currently stipulates **up to 3% deficits as a share of GDP and 60% debt/GDP ratio** (or decreasing at a satisfactory pace)
Surveillance	Greece is currently subject to **additional surveillance** under the **Macroeconomic Imbalance Procedure** (MIP), and in the context of post-assistance monitoring (does not include any significant restrictions)
EU semester	Coordinates SGP, additional surveillance frameworks and EC guidance on a recurring annual cycle (Nov. – Oct.) **providing member states with recommendations and coordinating policy priorities**
National escape clause	Member states may **request exemptions from fiscal rules** to deal with **exceptional circumstances**

Source: European Commission, Ministry of Economy and Finance

EU Health Policy Framework Overview

Recent EU health policy frameworks, coupled with available funding sources, provide a roadmap for Greece to invest in healthcare but have yet to be fully leveraged

EU legislation increasingly emphasizes the **need for bloc-wide coordination across regulatory frameworks, infrastructure development** and the **business environment**. Available fiscal space from recent overperformance, in conjunction with EU funding source availability, shown in table 3, can be effective tailwinds in implementing necessary reforms to the pharma sector in Greece.

Currently, Greece has been **prioritizing alignment with key EU directives** via implementing structural and administrative reforms.

Table 2. Key EU Directives in the Pharma Sector

Critical Medicines Act[1]	Drafting EU critical medicines list, streamlining regulatory processes, setting up **joint procurement** and providing incentives for **diversifying supply chains** including through state aid and strategic projects
EU HTA	Establishing an EU-wide body to perform Joint Clinical Assessments (JCAs), consult with Health Technology Developers. Aimed at **reducing duplication of clinical assessments** by national HTA bodies
EHDS	Common **dataspace** for secure access to primary & secondary health data with **interoperability and cross-border usage** as main priorities
Pharmaceutical Strategy for Europe	Legislation and strategy around **pharmaceutical production and innovation.** The strategy's main pillars include competitiveness, preparedness and affordable access

Source: European Commission

Table 3. EU Funding Sources for Health Reforms

European Investment Bank	Provides public sector loans for projects that align with its priorities; Eligible projects include R&D, infrastructure and providing universal access to safe and affordable care
Council of Europe Development Bank	Provides loans, grants and guarantees to co-fund public projects in a variety of areas including **health under the guiding principle of inclusion** and serving vulnerable groups
European Social Fund Plus	The **European Social Fund Plus (ESF+)** provides public entities with funding in a broad range of areas such as **healthcare in the scope of social inclusion**, education and employment

Source: European Commission, EIB, CEB

Note 1: 11 EU health ministers (incl. Greece) having been advocating for funding the CMA through the "ReArm Europe plan"

Comparison with EU peers

Greece shows a lower level of public pharmaceutical spending per capita compared to peers, with a disproportionate share covered by private sources

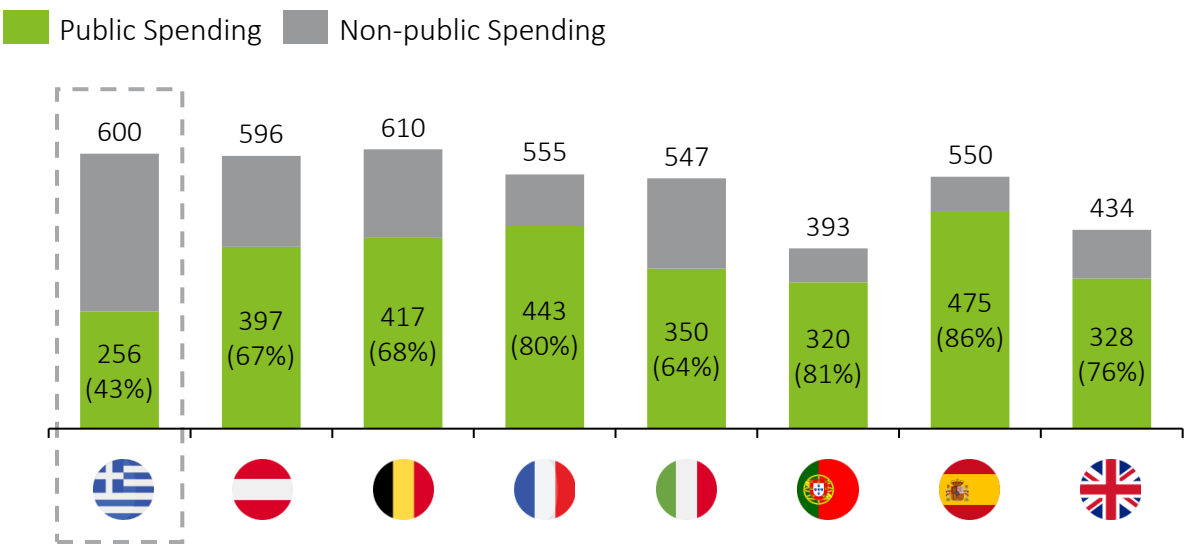
Despite efforts to stabilize access and maintain spending control, the structure of pharmaceutical financing in Greece remains imbalanced compared to other EU countries. A closer look at the data reveals a system characterized by **enhanced private contribution, limited growth in public funding**, and an ongoing reliance on **reactive rather than preventive health interventions**.

Heavy Private Contribution

In 2022, **pharmaceutical reimbursable[1] spending per capita in Greece reached €600**, placing the country close to the EU average in nominal terms. However, the composition of this spending is notably different: **only 43% was covered by public funding**, while **57% was borne by patients and other non-public sources**. This stands in contrast with peer countries such as France, Italy and Portugal, where **public coverage accounts for ~65–80%** of reimbursable pharmaceutical expenditure. The high level of **private expenditure** in Greece continues to raise concerns around **affordability, equity, and access**, especially for vulnerable populations.

Moreover, **public pharmaceutical spending per capita in Greece increased by just 5% between 2020 and 2022**, a modest rise compared to EU peers. In relative terms, public spending has grown **slower than GDP**, indicating a **progressive under-allocation of resources** despite growing needs.

Figure 8. Reimbursable Pharmaceutical Spending per Capita, 2022



20-22 reimbursable spending per capita growth, as a %							
22%	16%	21%	20%	17%	17%	18%	17%
20-22 public spending per capita growth, as a %							
5%	13%	6%	12%	10%	21%	11%	15%
20-22 GDP per capita growth, as a %							
18%	9%	10%	9%	15%	12%	13%	16%

Source: National industry associations, IQVIA, Economist Intelligence Unit, Deloitte analysis

Notes 1. Reimbursable spending refers to total spending, 2. The comparable countries were selected based on geography (South Europe) or data availability. The same countries were used for the identification of good practices

State of Industry Returns in the EU

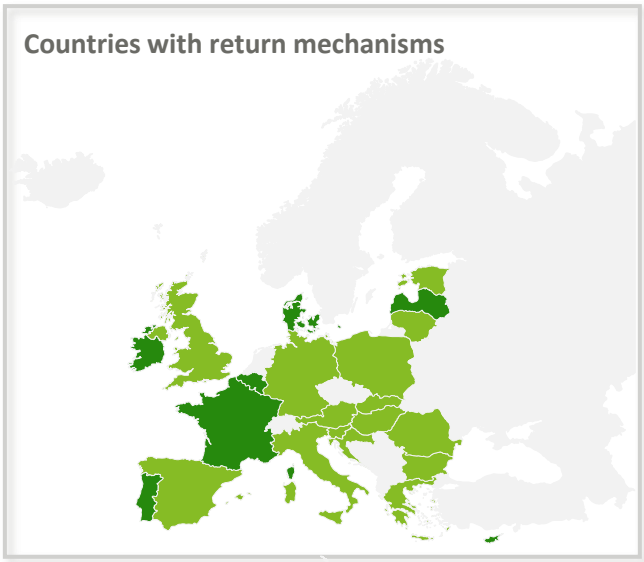
Unlike most EU countries where risk is shared, Greece places disproportionate burden of pharma spending on the industry, lacking structured agreements or offset mechanisms

Pharmaceutical return mechanisms have become a widely used tool across Europe for controlling public spending on medicines.

20 out of 30[1] countries in Europe have some industry returns mechanism …

… with **7** of them operating under a framework agreement, while others address pharma expenditure management under national strategies

Beyond the mechanism itself, the way **responsibility is distributed** between the state and the industry varies significantly across countries.



The Greek Case

In **most EU countries**, the financial burden from overspending is **shared**. The state often retains part of the responsibility, while companies participate under **clear rules and jointly agreed frameworks**. In contrast, **Greece applies a full clawback** on excess pharmaceutical spending, with **100% of the overshoot recouped from the industry**.

This unilateral approach creates a **disproportionate financial obligation**, which impacts investment predictability and limits the sector's ability to plan for the long term.

Source: SfEE, Desktop Research
Note: [1] Including EU 27 plus Norway, Switzerland and the UK

Framework Agreements

In some countries, the state has formalized cooperation with the industry through structured framework agreements.

These agreements include **safeguard clauses** and a clear division of responsibilities, allowing companies to operate within **predictable reimbursement terms**.

In Portugal, companies can **opt into the agreement voluntarily**, and those who participate contribute through a **clawback mechanism**, but are also allowed to **offset part of that contribution via R&D expenses**.

In these approaches, the contribution is linked to broader policy goals such as access and sustainability.

National Strategies

Other countries have embedded return mechanisms within national pharmaceutical strategies, aligned with sectoral objectives:

Spain's strategy (2024–2028) aims to manage spending by **promoting access to medicines, supporting innovation** and **ensuring long-term sustainability via strategic partnerships and framework agreements** that align public investment with sector growth and competitiveness.

Denmark seeks to **enhance efficiency and sustainability of pharmaceutical policies** by adopting **data-driven tools**, while **shaping long-term goals through collaboration** with industry and stakeholders.

Building the Gap (1/2)

Despite rising needs, public pharmaceutical spending was limited during the years of the financial crisis with industry covering the balance through return mechanisms

Over the past decade, the pharmaceutical funding model in Greece has been shaped not by structural planning, but by a series of reactive adjustments introduced during the debt crisis and the implementation of the MoU. These measures, adopted in the context of fiscal rationalization and austerity, gradually shifted the financial burden onto the industry. What began as a temporary response to severe budget constraints has since evolved into a system marked by limited public growth, policy inertia, and a disproportionate reliance on returns.

Compressed Public Funding

Between **2012 and 2015**, public pharmaceutical expenditure declined significantly as part of wider austerity policies. These reductions placed healthcare among the **top 10 fiscal policy priorities** monitored by oversight institutions at the time.

From 2016 to 2019, no incremental public investment took place, with public spending remaining flat despite rising pharmaceutical needs. The policy focus was on maintaining fiscal control, without structural recalibration or forward planning.

Industry contribution

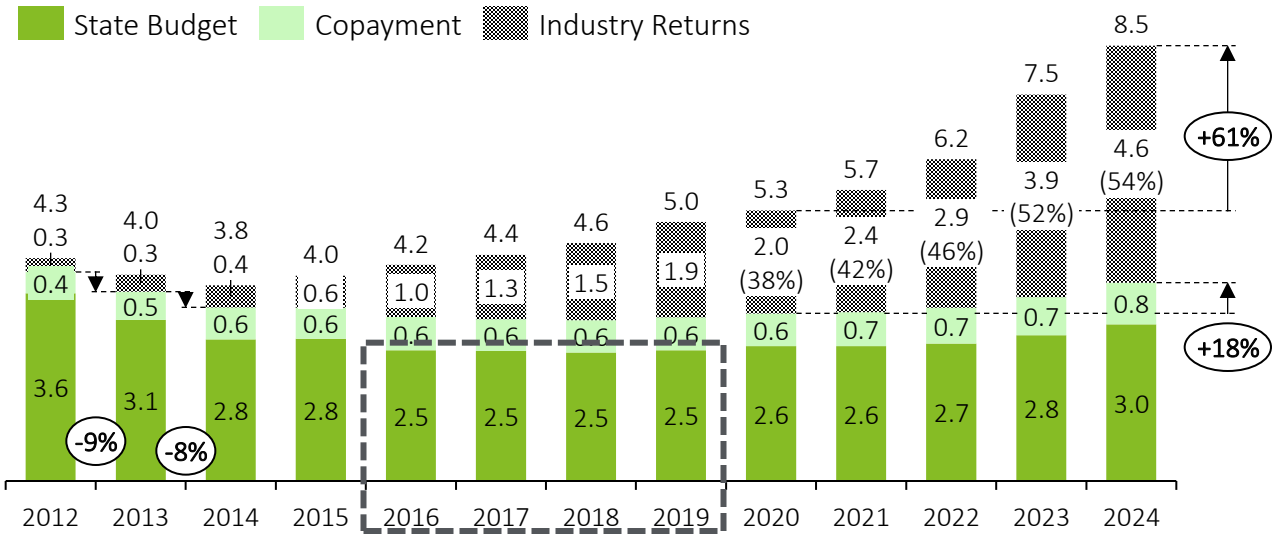
As demand rose and inefficiencies persisted, the gap was bridged not through reform, but via industry return mechanisms. From **2020 onward**, **public contributions remained stagnant**, while **returns expanded sharply**. **By 2023**, total reimbursable expenditure reached **€7.5b**, of which only **€2.8b (38%) came from the state**, while **€3.9b (52%) was covered by the industry**.

Importantly, the recent **increase in public spending was not the outcome of a needs-based assessment**. It reflected two key developments:

- The co-responsibility mechanism under the RRF, tied to European recovery funds,
- And a policy-driven adjustment following the country's GDP growth trajectory.

Looking ahead, public contributions are expected to grow by **~€100m annually on top of GDP-related increases and co-funding through the RRF (until 2027)**, but **without deeper reform**, the financial pressure will continue to fall disproportionately on the industry.

Figure 9. Reimbursable Pharmaceutical Spending, in €b



Source: EOPYY, SfEE

Building the Gap (2/2)

A decade of dense reform activity failed to deliver structural rebalancing, leaving inefficiencies and fragmentation in place

Over the past decade, Greece has implemented a wide range of reforms across the pharmaceutical and health system. While these measures were often presented as steps toward modernization, the absence of a long-term strategy and institutional coherence meant that **most reforms remained technical, reactive or incomplete**.

Early Reforms (2012–2015)

Initial reforms were driven by the need to contain public spending under tight fiscal targets. Measures such as **rebate and clawback, the establishment of EOPYY and the introduction of electronic prescribing** aimed to improve control and monitoring. These were accompanied by structural tools like **INN prescribing, DRG-like costing in hospitals** and **a closed cap for pharmaceutical expenditure**.

Although these interventions improved oversight, they did not address the system's ability to plan or adapt. **Initiatives that promote efficiency were not prioritized** and spending control was primarily enforced through ceilings and restrictions.

Reform Push (2016–2019)

In the years that followed, reform efforts focused on **administrative streamlining** and **access expansion**. Initiatives included primary care reform through introduction of **PEDY, prescription protocols, Gx targets**, and the **extension of healthcare access to uninsured populations**.

New structures such as the **Negotiation Committee** and **Electronic Pre-approval System** were introduced, and **EKAPY** was established to centralize procurement. However, none of these reforms fundamentally changed the **budget structure, governance model, or cost-sharing mechanisms** in the system.

Control Mechanisms (2020-2024)

In recent years, **control mechanisms intensified** through **pricing reforms, hospital clawback protections** and **budget split**. At the same time, **positive steps** were taken with the **introduction of investment clawback** in 2020, aiming to enhance system's reciprocity and enabling investments. However, broader efforts to structurally rebalance the system and establish a stable, transparent environment that enables long-term planning and reduces uncertainty remain limited.

As pharmaceutical needs increased, the burden of inefficiencies continued to fall disproportionately on the private sector. **Policy evolved reactively**, responding to fiscal pressure with containment tools, rather than long-term planning, **increasing the system's complexity** and further weakening its coherence.

Source: EOPYY, SfEE, Desktop research

A Cycle Sustained by Adverse Incentives

The industry returns mechanism sustains a vicious financing cycle which creates moral hazards for key stakeholders, culminating in a series of paradoxes

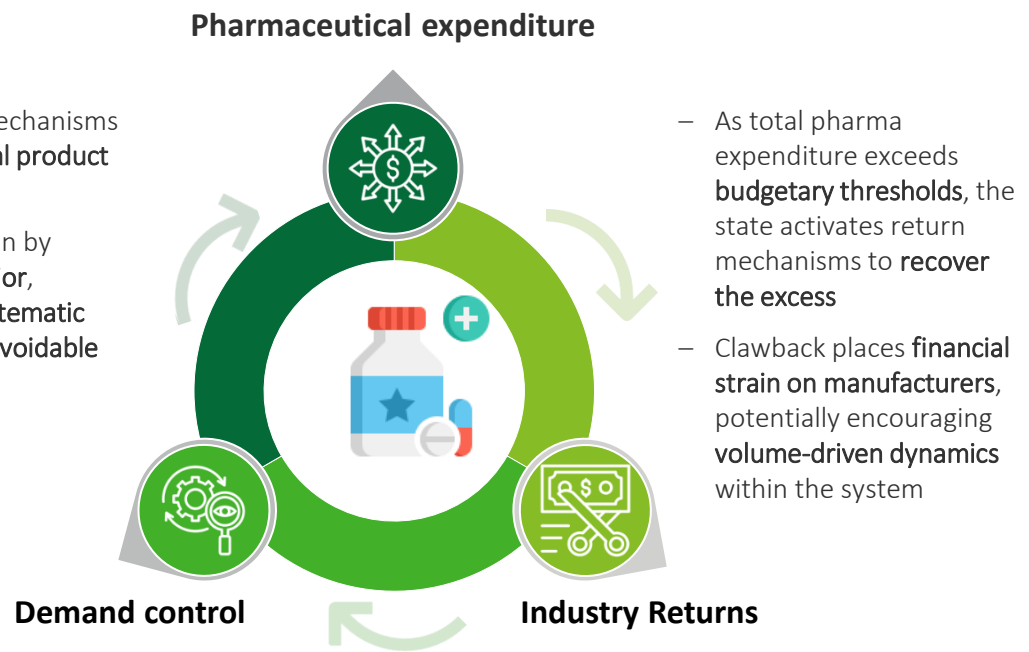
Introducing industry returns as a fiscal balancing measure in an environment where reimbursable spending increases faster than public spending created a **vicious cycle of adverse stakeholder incentives** which can lead to moral hazards and render the pharmaceutical system unsustainable with negative effects to patients' health.

On the state's part, there is a **lack of incentive to proactively manage consumption and spending** due to the existing **fiscal balance provided by returns**. This risks institutionalizing ad hoc and reactive regulatory and fiscal policies which can **compromise value-based decision making** found in most major EU health systems (See Appendix II on EU good practices).

The lack of proactive planning and monitoring by the state coupled with behavioral and supply considerations disincentivize a cost-effective, clinically sound mindset leading to **wasteful spending** in terms of product mix and avoidable costs.

Return mechanisms ensure fiscal sustainability independent of any additional waste the system has accumulated, placing an **ever-increasing strain on manufacturers** and introducing a potential moral hazard in the form of volume-driven competitive dynamics that further undermine the industry's sustainability.

The hazardous financing cycle has **created and sustained a series of paradoxes** which imply contradictory policies in numerous areas.



– Return mechanisms provide **a fiscal buffer**, reducing the **urgency for the state** to invest in **structural demand-side controls**

– Over time, this reliance on **financial corrections risks** institutionalizing **reactive management**, making it harder to shift toward proactive, **value-based reforms**

Showcasing the System's Paradoxes

For an external observer, the Greek system is characterized by a series of paradoxes

Lowest Prices with Highest Returns

Greece has some of the lowest on-patent prices (based on ERP) for pharmaceuticals in Europe while maintaining the **highest industry returns in absolute and percentage terms** in recent years. This miss-match between Greece and the rest of Europe (See figure 8) implies a combination of **historical underfunding** and **inefficient resource allocation** in the system.

Growing Returns despite Public Spending Increasing

Public pharmaceutical spending has increased in recent years, mostly through utilizing EU funding. While this is a move towards the right direction, the amount of **additional funding has fallen short of total reimbursable spending growth**, thereby increasing returns in absolute and percentage terms. This implies the use of **additional public funding has been insufficient** to tackle the system's inherent weaknesses.

Price Rules vs Return Variance

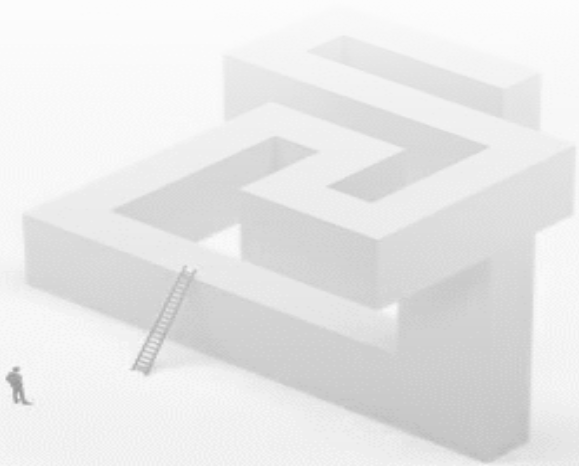
Despite having a consistent pricing methodology, **return levels differ significantly across channels**. This is largely driven by **structural factors**, such as clawback protections that are applied unevenly, budget fragmentation and inconsistent sub-budget enforcement, that undermine predictability and distort the investment environment.

Industry Funds Care and Policy Gaps

Under the current framework, where return levels continue to escalate, **any new policy introduced without a corresponding increase in public pharmaceutical funding leads directly to higher industry returns**. In practice, this means that the industry ends up absorbing the cost of healthcare and social policies, effectively financing both access expansions and unmet system needs. This dynamic is further exacerbated by the **growing role of IFET** and the **absence of systemic demand management**, creating misalignment between policy formulation and available budget.

Unlike EU Trends, Complexity Increases

EU trends lean heavily towards **simplified budget systems**, opting for 2-channel systems and **avoiding differential treatment** between broad categories of medicines. Greece appears to be an **outlier in terms of the complexity of budget splits** and **differential returns policies within channels**. These policies are often implemented in reaction to unexpected consumption patterns, apply retroactively and contribute to the disproportionate returns burden placed on some manufacturers. The shift from budget sufficiency and efficiency to allocation of existing resources creates conflicting agendas, harming the industry's competitive environment.



Industry Returns' Market Distorting Nature

Growing return levels result in reduced net sales for organizations that maintain constant gross sales

Hypothetical Returns Example

Using 2023 as a reference year and with the utilization of 4 growth scenarios for a representative "Company A", the example's aim is to showcase the disproportionate effect of industry returns on no- or low-growth companies. **Assuming company A maintains a constant product and volume mix, is subject to the overall returns rate and with gross revenue of €100 in 2023.**

Takeaways

As shown in Figure 10, if a company does not achieve growth over the period, it loses a portion of net sales. This points towards an increasingly complex business landscape which places a **growing burden on companies that don't grow at par with the market**, in an environment where reimbursable spending growth consistently outpaces public spending growth.

Table 4. "Company A" Growth Scenarios, %

Decline	-10%
No growth	0%
Moderate Growth	10%
High Growth	20%
Market Growth	12.6%

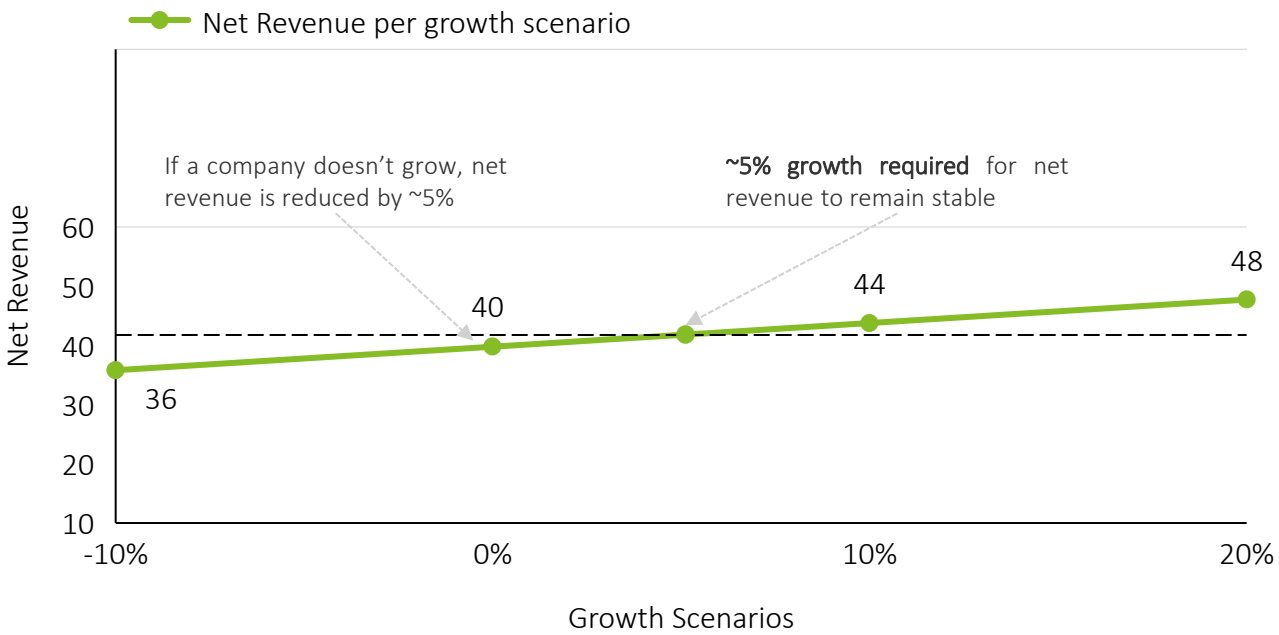
Table 5. Total Market Parameters, €m

	2023	2024
State budget	2,832	3,040
Returns	3,933	4,602
Returns rate[1]	58%	60%

Note[1]: Returns rate calculated by excluding copayment

Source: SFEE – IOBE

Figure 10. "Company A" Net Revenue, in €m and 2023-2024 growth scenarios



Source: SfEE, IOVE, Deloitte Analysis
Note: This example is a simplification aiming to showcase the issue

Zoom in on Industry Returns per Channel

The retail channel corresponds to 39% of total spending but generates only 23% of returns which is partially attributed to the way retail prices are built up

Table 6. Reimbursable Pharmaceutical Expenditure, in €b

2023 figures	Retail	EOPYY Pharmacies	Hospital	Total
State budget	€1.3b *(60%)*	€0.9b *(39%)*	€0.6b *(27%)*	€2.8b *(42%)*
Industry returns	€0.9b *(40%)*	€1.4b *(61%)*	€1.6b *(73%)*	€3.9b *(58%)*
Subtotal	**€2.2b**	**€2.3b**	**€2.3b**	**€6.8b**
Copayment	€0.7b	-	-	€0.7b
Total	**€2.9b**	**€2.3b**	**€2.3b**	**€7.5b**
Industry returns (as % of total)	*30%*	*61%*	*73%*	*52%*
		+31%	*+43%*	

Source: EOPYY, SFEE, Desktop Research

Funding Sources

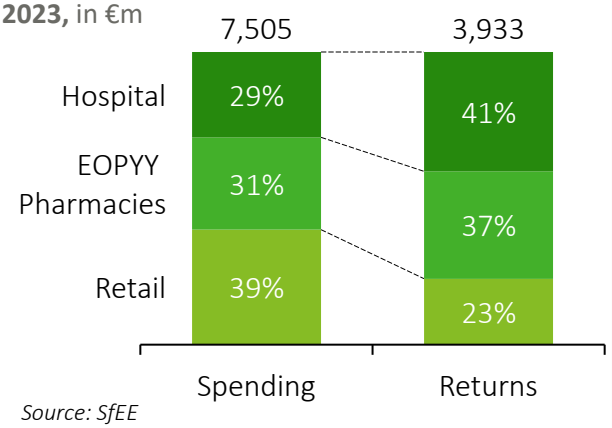
Table 6 presents 2023 figures for each channel, broken down by funding source, showcasing the **uneven distribution of returns among channels**, a culminating to the hospital channel now paying more than twice the returns rate as the retail channel.

Industry Returns Zoom in

Industry returns in Greece currently place a **disproportionate burden on specific segments** of the pharmaceutical market, exacerbated by the unequal distribution of additional public funding and protections to some segments in recent years. As presented in Figure 11, **hospital and high-cost medicines are subject to returns rates that are higher than their contribution to reimbursable spending**.

The unequal treatment between channels **risks compromising equal access for patients** depending on their geographic location and the distribution channel through which they receive the medicines they rely on.

Figure 11. Spending and Returns per Channel 2023, in €m



Source: SfEE

Where we Stand Today

Recent priorities indicate a reform-oriented path, although efforts are fragmented and implementation continuity remains a key challenge

Recent Pharmaceutical Policies

Since early 2024, various Ministry of Health officials have announced proposed pharmaceutical policies in a broad range of focus areas. Some of these policies are in the right direction but **most have yet to be implemented,** or their effectiveness was diluted due to other stakeholder considerations. Based on measures announced over the period 01/2024-05/2025, the perceived priorities of the MoH leadership are presented in Table 7.

Implementation Considerations

Monitoring capabilities

The development of internal **tools and processes for monitoring** pharmaceutical consumption and spending is considered **limited**, affecting the system's ability to track progress and implement adaptive policy responses.

Reduced Incentives due to Industry Returns

Industry returns offer fiscal predictability and stability to the state budget, leading to reduced incentives for structural reforms and system redesign. This **lack of incentive plays a key role in the sustained nature of the system's inefficiencies**.

Ad hoc, Reactive Nature of Reforms

Various fiscal and regulatory measures were enforced on a **retroactive basis** when implemented. Moreover, their ad hoc nature paint an overall picture of an **unpredictable environment with gaps in long-term strategic planning and policy continuity.**

A list of publicly available policy announcements compiled from news sources from 2020 onwards is available in Appendix I.

Table 7. Perceived Government Priorities, 2024-today

Government Priority	Indicative Measures
Digitalization	– **National EHR is being developed rapidly** for HCP and patient uses – **National Oncology Registry** currently in pilot phase
Innovation	– Separate budget for **reimbursing cancer biomarkers** – Announced intention to introduce a **transitional reimbursement fund**
Demand Management	– **Protocols** through e-prescription system launched but **effectiveness has been limited** – Abolished equation of retail with reimbursement price, €3 limit
System Integrity	– Announced that **Inactive SSNs** and the uninsured will only be eligible for emergency care – **DRG costing system** currently being implemented

Source: News Reports and Official Announcements

Interviews with External Stakeholders

Stakeholders consistently highlight structural weaknesses across multiple dimensions of the healthcare system, signaling the need for coordinated, system-wide transformation

"***Trust*** *remains a* ***core challenge*** *in the healthcare system"*

"***Lack of cultural change*** *in both physician and patient behavior drives persistent* ***overuse and inefficiency***"

"***Clinical-only evaluation*** *of therapeutic protocols leads to* ***cost-inefficient treatment*** *choices"*

"***Investment in infrastructure*** *is key for Greece to become a* ***clinical research hub in the Balkans***"

"***Retrospective doctor controls are not sufficient*** *— real-time oversight of clinical decision-making is essential"*

"*Exploring* ***alternative funding mechanisms*** *is essential for ensuring system sustainability"*

"*Although* ***access to innovation*** *aligns with the EU average, our performance* ***lags considerably*** *behind that of best-performing countries"*

"*Without* ***data integration and EHR connectivity****, reform efforts remain fragmented and inefficient"*

"***Delays in reform and investment*** *may cause Greece to* ***miss the innovation momentum*** *in pharma"*

"***Fragmented measures*** *that do not fall under a broader and robust strategy, result in* ***limited impact*** *and* ***reform stagnation***"

"***Lack of prevention investment*** *undermines* ***future health outcomes*** *and reduces the* ***long-term productivity*** *of patients and caregivers"*

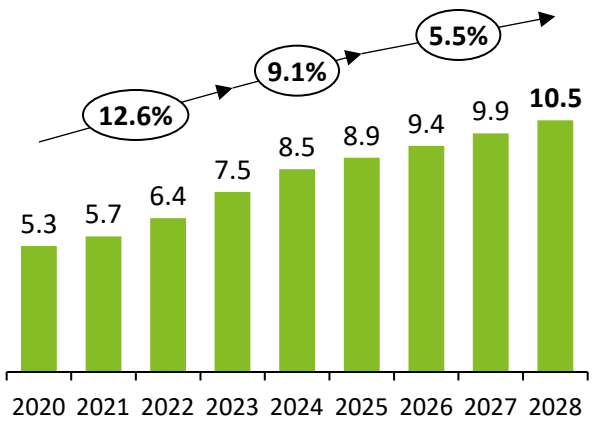
The way forward

Discussion frame

40% industry returns is a fair target state, meaning a €1.5b balance must be dealt with to reach the target by 2028 based on the current trajectory of spending

Continued spending growth

Figure 12. Reimbursable Spending, in €b



Source: SfEE, IOVE

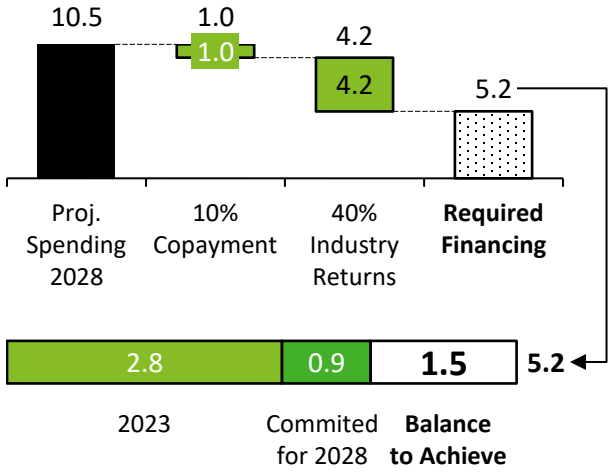
Despite increased public funding, **returns increased from 38% to 54%** between 2020 and 2024. Patients **paid €810m in copayments in 2024** compared with €640m in 2020, amounting to a ~**27% increase** over the period. This trend is expected to continue, with **total spending expected to reach €10.5b by 2028**.

A reasonable goal

While not ideal, 2020 is seen as a fair base of comparison to the "do nothing" scenario that results in €10.5b total spending. This year was selected as it was the **first full year of governance** for the current administration, whereas it marked the **beginning of the RRF program** which continues to have an impact on public spending. Furthermore, **40% returns** were an all time high at that point. Finally, looking into the financing patterns, it appears that 3 years were enough to go from 40% to 50%+; thus, 3 years ahead should be enough to reverse the trend.

Balance to achieve the goal

Figure 13. Required Financing, in €b



Taking projected spending as a starting point and fixing copayments and returns as a percentage of total spending, we can see that total required financing is €5.2b to reach the goal by 2028. Based on public spending increases currently committed through 2028, a balance of €1.5b must be closed within the next 3 years.

The way forward

There **are 3 options** to deal with the financing gap, as described above:

- Increase public spending by the **entire balance to achieve,** reaching a rational financing structure without affecting total spending
- Decrease total spending such that **returns reach 40% in 2028**
- **Concurrently increase public spending** while **decreasing total spending** to reach 40% returns

Problem decomposition

Examining the root causes of high returns reveals that a suboptimal mix caused high total spending, while public spending inefficiencies contributed to the funding gap

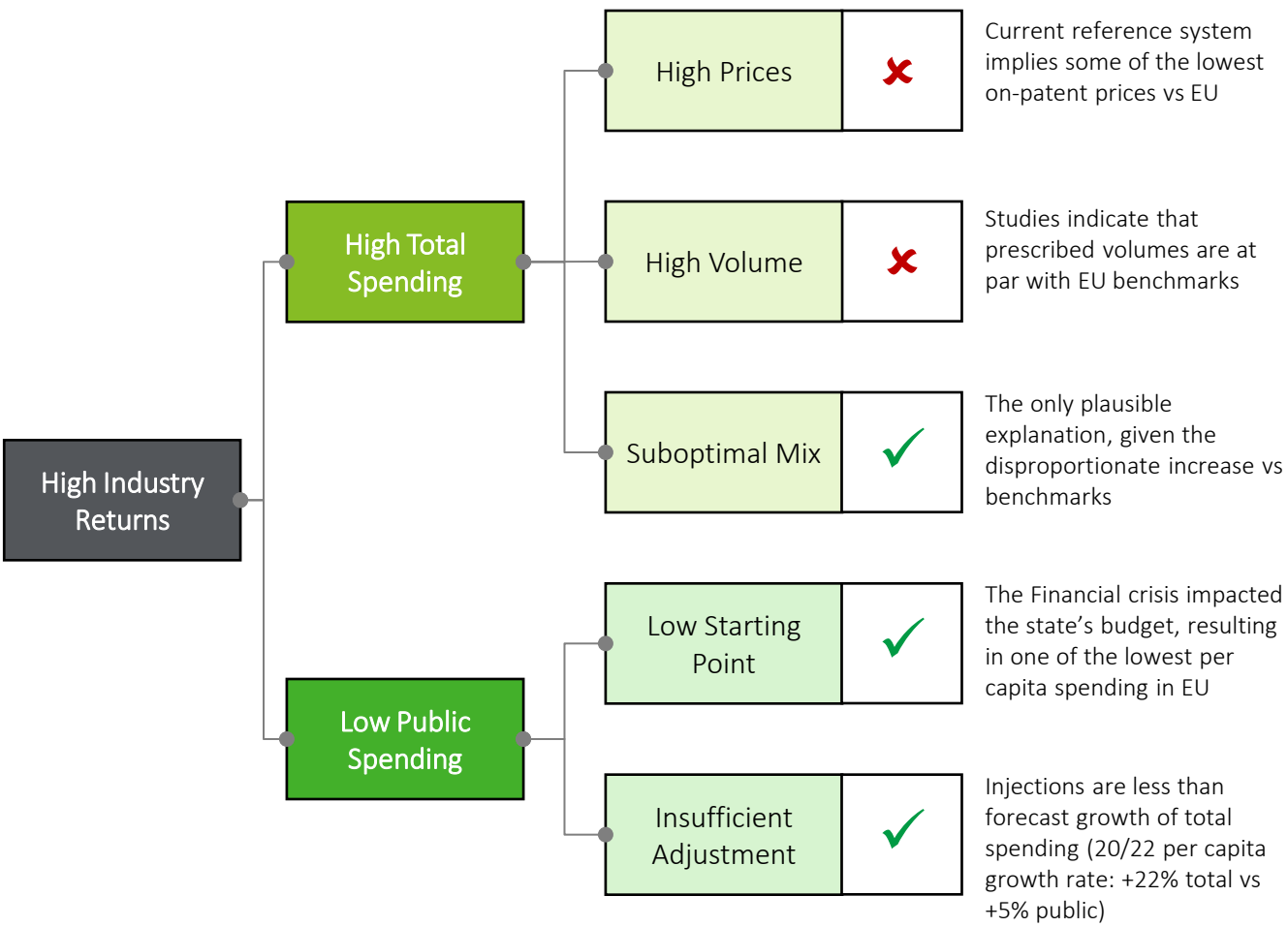
Zooming in on the issue of industry returns, we can **decompose the problem into its potential root causes** to reveal what caused the growth gap between public spending and total spending over the years.

The observance of high industry returns can only be caused by **high total spending** (relative to public spending), or **low public spending** (relative to total spending). By breaking down each of these sources of industry returns to their component parts we can triangulate the possible causes in Greece's case.

In terms of high total spending, pricing and volume don't show any signs of being a source of growing total spending.

This leaves a **suboptimal mix as the plausible area of intervention**. The lack of discipline in the system can be dealt with through interventions such as prescription protocol implementation and a co-responsibility mechanism.

Diagnosing low public spending through historical analysis also reveals that **public spending remained stagnant for multiple years** in which total spending inherently increased, while **increases to the public budget since then haven't kept up pace** with total spending growth.



Source: WHO pharmaceutical pricing and reimbursement information, Institute for Health Economics, SHA, National pharma associations, SfEE, IOVE

Strategy Conceptualization

A holistic strategy requires clear vision, measurable targets, defined responsibilities, concrete actions, and strong collaboration

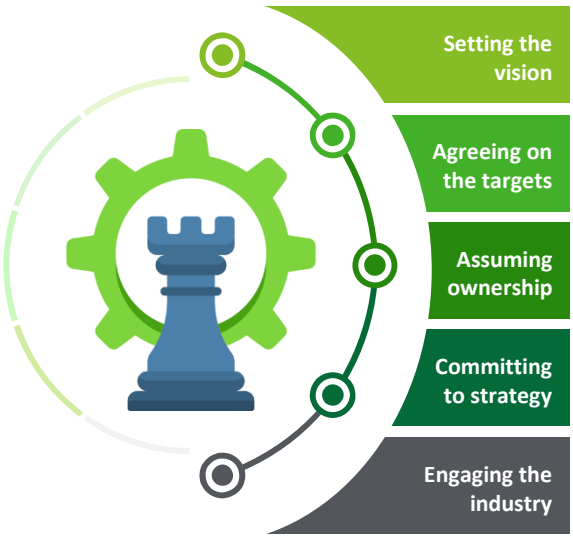
To present a way forward for the pharmaceutical system, a **comprehensive strategy** was crafted based on the analysis and multistakeholder points of view presented in earlier sections. Comprised of **5 building blocks**, it focuses on **setting qualitative and quantitative targets** and provides **proposals on reaching those targets**, with extensive examples of similar initiatives that have been successful in comparable health systems.

The strategy's first component is grounded in **shared principles** and aims to establish a **commonly agreed vision and set of values between the state and the industry**. It involves defining a clear and actionable direction, underpinned by **key strategic imperatives to guide future actions**. A critical part of this step is to articulate what 'good' looks like through a set of measurable KPIs, free from value judgments or bias toward specific stakeholder interests.

The next component involves **establishing a dual spending target** (increase public spending while decreasing total spending). The targets should be based on **what is agreed upon as reasonable and feasible** within a medium-term time frame. Closely linked to this part of the strategy, the **spending targets that are agreed upon must be owned by all stakeholders involved** through monitoring and corrective mechanisms in case targets aren't being met.

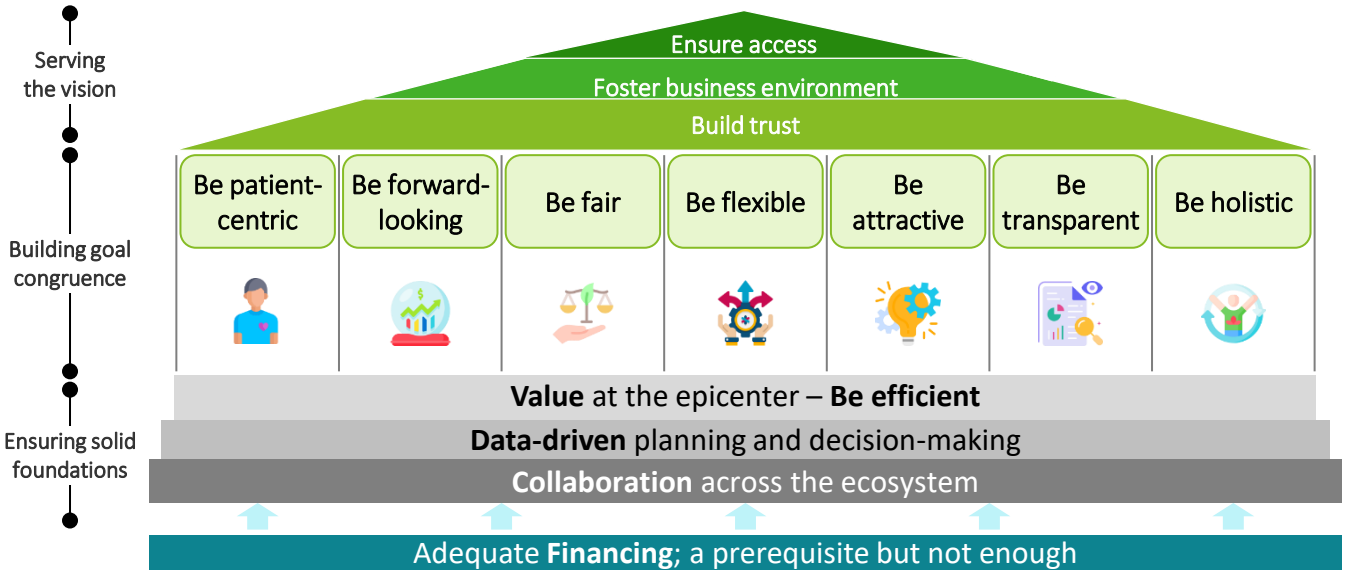
After setting and committing to financing targets, **a set of detailed initiatives having high impact in meeting financing targets and transforming the system are required**. The initiatives must be well rounded to enable value creation from early on, while being well thought out to fit the system as it transitions to a more desirable state for all stakeholders.

Finally, the system requires the **establishment of reciprocal mechanisms across the ecosystem**. This includes a more **structured and collaborative approach between the state and the industry**, leveraging the industry's capacity to support the design and implementation of key initiatives. At the same time, it is essential to create **meaningful incentives that encourage new and expanded economic activity and reward long-term investment**.



Setting the vision

Strategic imperatives must be paired with clear performance indicators, ensuring that all actions contribute to long-term system efficiency, universal access and equity



Imperative	Description	Indicative KPIs
Be patient-centric	Promote equitable and timely access to the right solutions	• Ensure that Greece is above EU average for full access to innovative treatments
Be forward-looking	Build a plan, stick to it and examine / explain variances	• Have rolling 3-year projections per channel – total spending, budget financing
Be fair	Treat all products / channels equally; convergence	• <10% return deltas among channels • Identify fiscal space for interventions
Be flexible	Build corrective mechanisms to manage imbalances	• Allocate 5%-10% of projected budget to balance the system
Be attractive	Establish an investment value proposition	• 5% YoY increase in Gross Fixed Investment • 10% YoY Increase in number of clinical trials
Be transparent	Share data through open and secure platforms	• Build HDPA to share health data securely • Provide underlying data to back up policies
Be holistic	Optimize value across the health ecosystem breaking the silos	• Identify, quantify, leverage and test correlations for spending and policy
Be focused on value	Maximize cost-effectiveness	• Incorporate value in negotiations, especially for market segments such as innovation
Be data-driven	Leverage modern infrastructure	• All future decisions backed by data • Leverage secondary data to create value
Be collaborative	Foster structured cooperation	• Institutionalize a platform for formal dialogue among stakeholders

Balancing the system

Targets should focus on increasing public financing and decreasing total spending to yield 35-40% returns, backed by a corrective mechanism to ensure goal congruence

Dual Spending Target

To balance pharmaceutical financing in Greece, a **dual spending target** is required:

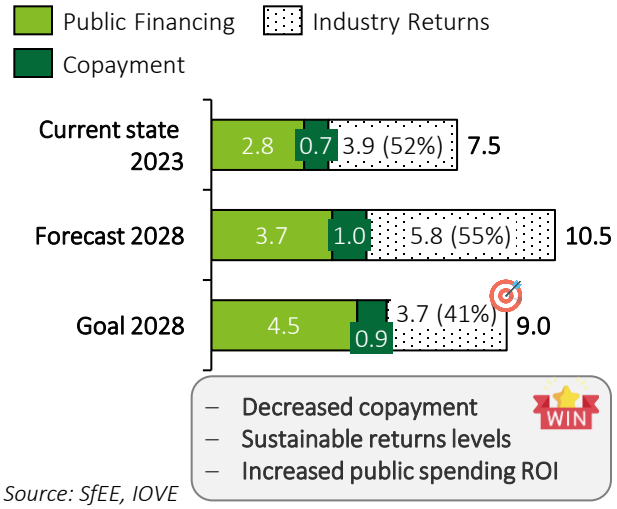
Total Spending Decrease

With total spending forecast to reach €10.5b by 2028, the goal is to **achieve a €1.4b reduction in total spending**, amounting to **50% convergence** between the current state (2023 – €7.5b) and the projected state for 2028 ("Do nothing scenario")

Public Spending Increase

The **goal is for public spending to keep pace with total spending growth forecasts**. Given the 2020-2028 total spending CAGR (target state) is 7%, public spending should **increase to €4.5b by 2028**.

Figure 14. Reimbursable Spending, in €b



Source: SfEE, IOVE

Co-responsibility Mechanism

Figure 15 presents **a conceptualization of a proposed co-responsibility mechanism for ensuring progress towards the dual spending target**. The example shows **how annual budget planning will remain unimpeded** by incorporating the state's share of excess spending to the next year's budget, rather than retroactively increasing it for a given year. A **progressive scale for the state's share of excess spending** is included (See an indicative example in Table 8), while **spending targets will evolve and incorporate new information to avoid overshoots**. Finally, it should be noted that **co-responsibility has been utilized in Greece in the context of the RRF**, while Appendix II includes a collection of co-responsibility good practices.

Figure 15. Proposed Co-responsibility Mechanism

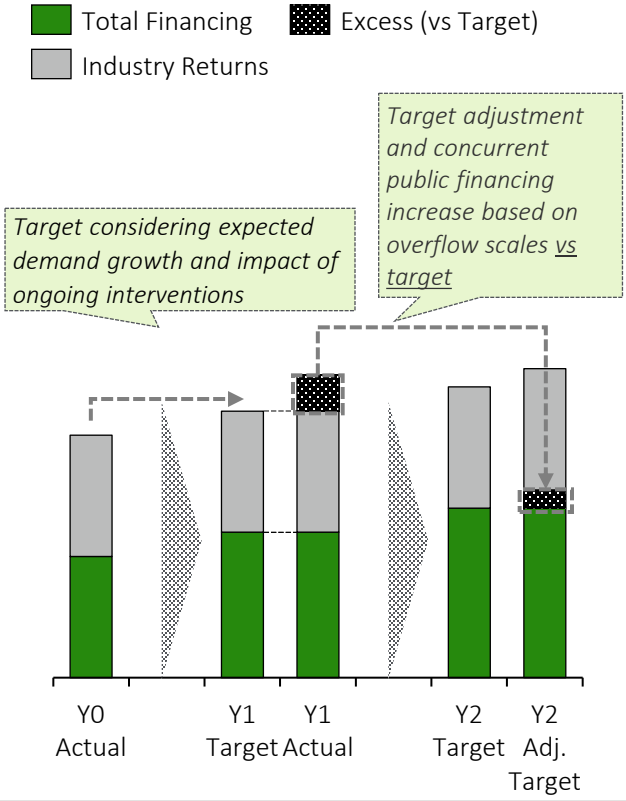


Table 8. Example co-responsibility scale , in €m

Excess vs target	Industry	State
<€100m	100%	0%
€100-200m	75%	25%
>€200m	50%	50%

Note: [1]Total Financing = Public Spending + Co-payment

Strategic Roadmap

The road towards the desired state goes through a set of interrelated reforms allocated in 3 primary groups, each with a clear overarching theme

The cornerstone of the strategy is a set of **substantiated suggestions** which were identified as having high impact in meeting financing targets and moving towards the vision based on a health system's imperatives, described in page 35. Each proposal is presented along with an introductory presentation of the issue it relate to, and an analysis of key implementation considerations and indicative benefits from pursuing the initiatives. They are **grouped into 3 categories:**

Bridging the Financing Gap

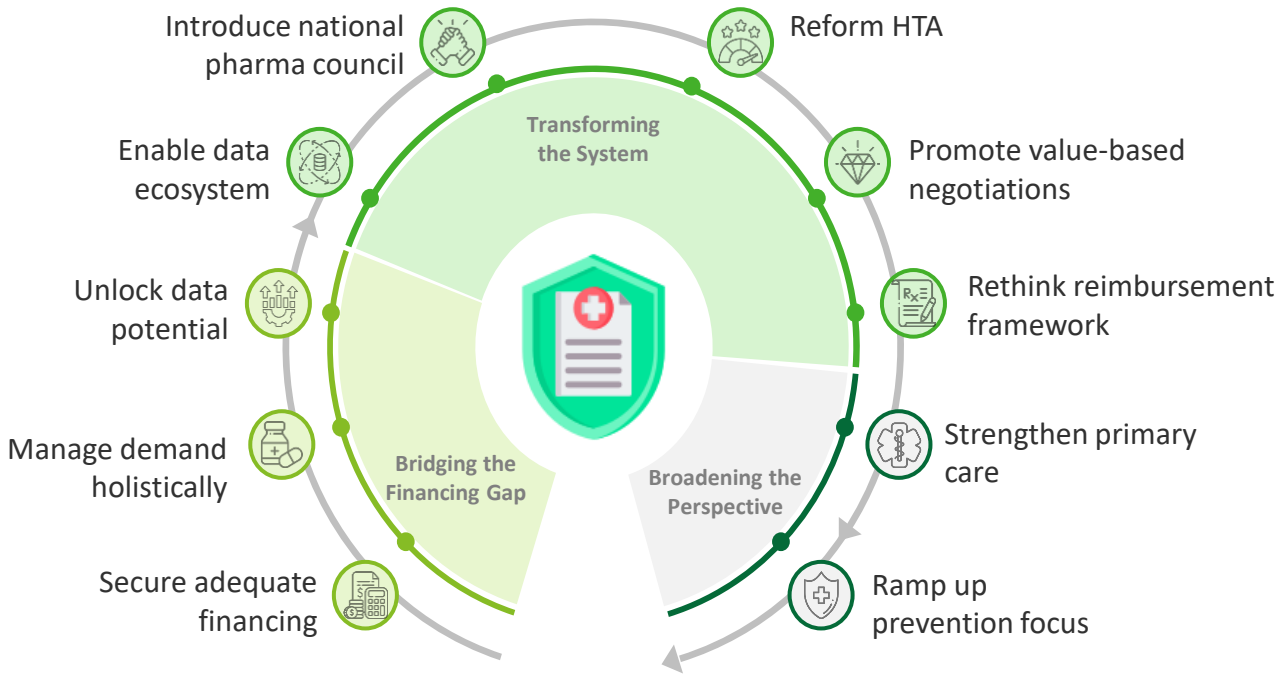
Aimed at directly contributing towards decreasing reimbursable spending while helping to identify how public financing is spent and where there is waste. These proposals acknowledge that additional public financing is not sufficient to alleviate the pressures on the industry and the health system. Their main goals are to introduce mechanisms to **gain understanding of** and **resolve the sources of excess spending**.

Transforming the System

A series of **structural reforms and projects** that create long-term sustainability and **tackle the hazardous cycle** that sustains the system's paradoxes described in pages 25-26. These initiatives are focused on **aligning** the Greek pharmaceutical system **with best practices and EU directives** while setting the stage for a system that can proactively plan for future needs without unnecessary complexity and ad hoc measures.

Broadening the Perspective

The third group of proposals **focuses on strengthening primary care and expanding preventive health measures** through well-designed, cost-effective interventions. These aim to proactively **address disease onset and progression**, **reduce long-term system burden** and **embed a truly value-based mindset** in public health policy planning.



Bridging the Financing Gap

Secure Adequate Financing

Unstructured overflow spending distorts pharmaceutical financing, undermining fiscal discipline, transparency and system's responsiveness to real needs

Current State

Despite the existence of a budgeting framework, pharmaceutical financing falls short of evolving and unforeseeable needs. This **leaves the available budget overburdened** and unable to proactively plan for unexpected sources of spending, including innovative medicines that solve unmet and pressing needs.

In this context, current financing falls short along these dimensions:

- **Overflow mechanisms**,, such as screening programs and extended breadth of care which create excess spending but are not considered during the budgeting process
- **IFET**, which operates outside standard planning, while associated returns are covered by EOPYY, limiting system reinvestment
- **Innovation funding,** which has become more of an issue as new medicines take longer to reach Greece

The current state of financing creates uncertainty for manufacturers and indirectly **fuels increased reliance on alternative channels and industry returns.**

source: IOVE

Why it is important

Securing adequate funding is **critical to ensuring sustainability and fairness** in pharmaceutical financing. The lack of formal mechanisms that allocate spending to the most pressing needs **limits predictability** and weakens the system's ability to plan in the long-term.

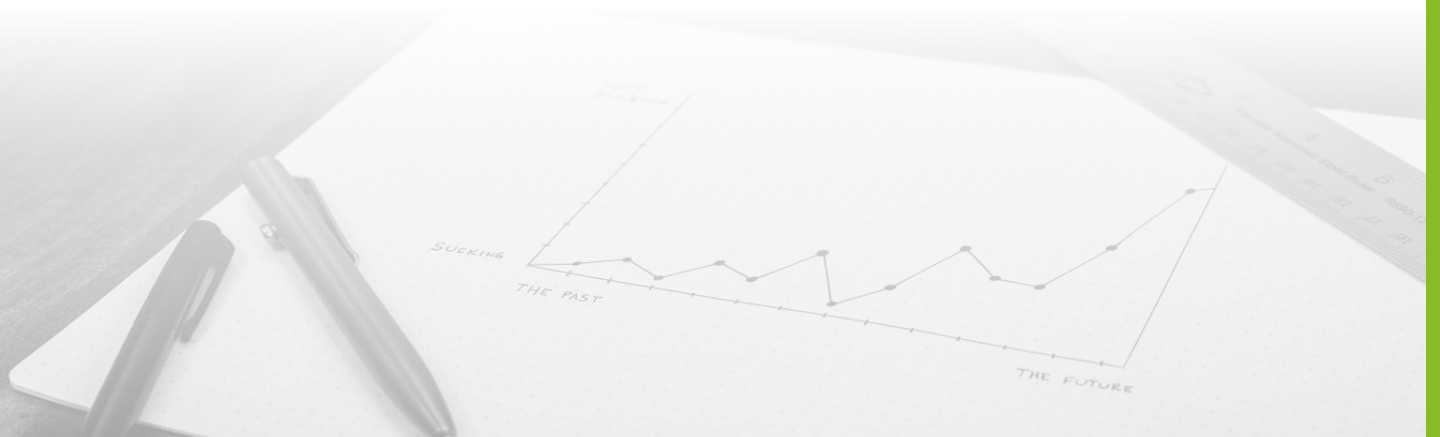
Integrating **evidence-based budgeting and monitoring tools,** including a dedicated innovation fund, will improve resource allocation, support fiscal responsibility, and align spending with **value-based principles**, reinforcing transparency and equity across the system.

Proposal's Rationale

The proposal introduces a **structured and data-informed approach** to determining and dealing with ad-hoc financing needs. It suggests **distinct budgeting tools, clear accountability** and enhanced oversight to treat these costs systematically, rather than as exceptions.

Targeted actions include financing uninsured population's access from alternative sources, isolating impact of protective measures and **prevention-related spending, and introducing dedicated innovation funding** to ensure alignment with broader system goals.

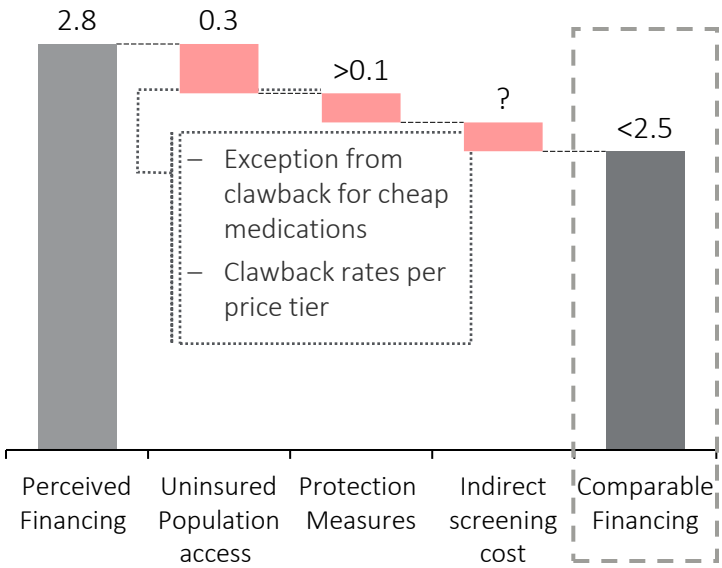
The approach enables more **accurate forecasting**, improves flexibility and strengthens **transparency** in how public resources are used.



Secure Adequate Financing

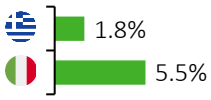
Overflows change baseline projections and require incremental financing, while IFET's framework should be revisited, and innovation funding should be expanded

Proposal conceptualization



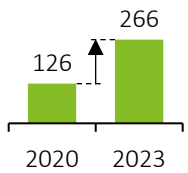
The introduction of an innovation fund is a positive step; yet initial financing is considered limited compared to market needs

IF, as a % of state budget *(2023 figures)*



Even though, IFET's role & financing should remain intact, the organization is considered an overflow, as it effectively reduces available financing

IFET Sales, in €m



Area	Proposal
Uninsured population access	Decrease overall spending by deactivating inactive SSNs & increase of financing through social affairs funding
Protection Measures	Measure anticipated industry returns generated if not for protection & con-current budget increase
Indirect Screening Cost	Create prevention bucket within public spending (with additional financing) to cover indirect cost of screening programs
Innovation fund	Establish clear guidelines and mechanics on market entry, while gradually increasing to converge with Italy case study
IFET	Increase transparency into the operations (e.g., inclusion criteria) and scrutinize products that systematically come from IFET

Case Study Highlights

Uninsured population treatment

Benefits to uninsured population provided through social expense. (separate budget)

Screening programs economic evaluation

NICE guidelines for screening programs assume both direct screening cost as well as indirect based on assumptions on population that will require follow-ups.

Innovation fund

Financing Breakdown: €0.9b to fully innovative, €0.3b to conditionally innovative, €0.1b to reserve antibiotics (2025):

– Includes criteria considering technology (biologic, ATMP)

– Utilization as a channel for up to 3 years per product

– Preferential treatment depending on level of innovation

Secure Adequate Financing

For overflows to be managed separately from the budget, specific methodologies alongside monitoring should be employed, ensuring effectiveness in public financing

Key Implementation Considerations

Fiscal Space Identification

Managing overflows implies an increase in public expenditure. Identifying viable sources of funding is essential in a constrained fiscal environment. This step ensures overflows are managed without compromising other budgetary priorities.

Budgeting Methodology

Developing a standardized methodology to embed overflows into the broader budgeting framework is necessary. Evidence-based forecasting models can support more accurate planning and integration of overflows in a way that reflects actual needs.

Monitoring Mechanisms

The implementation of real-time monitoring tools integrated into the digital infrastructure of public financing is critical. Such systems would enhance visibility over expenditure, enabling early detection of deviations and timely corrective actions.

Innovation Fund Mechanics

Define eligibility criteria and set transparent entry and exit rules for therapies financed through an innovation fund. Establish a clear governance structure to oversee fund operations, ensuring alignment with broader policy priorities.

Anticipated Impact

Increased Effectiveness

By managing overflows independently from baseline financing, public funds can be directed more deliberately, enhancing spending efficiency. This structured approach reduces ad hoc adjustments and allows for prioritization of high-impact needs.

Improved Flexibility

The adoption of overflow-specific budgeting enables the state to dynamically respond to emerging needs. Real-time expenditure insights support agile resource reallocation and contingency planning, reducing rigidities and allowing for financial governance.

Enhanced Transparency

Clear delineation between standard budgets and overflow expenditures improves visibility for all stakeholders. This facilitates a fairer negotiation framework, strengthens trust in the system and supports long-term sustainability.

Accelerated Access to innovation

A dedicated innovation fund enables faster inclusion and reimbursement of novel therapies through structured eligibility and evaluation criteria, improving responsiveness to medical advances.

Initial implementation timeline

12-24 months

Address Demand Holistically

The inefficiencies of pharmaceutical demand have driven irrational prescribing which risks limiting patient access and contributing to ineffective public spending

Current State

Despite ongoing efforts to manage pharmaceutical expenditure, **Greece lacks a structured, transparent framework to guide and monitor pharmaceutical demand**. While steps have been taken to link the budget with evolving demand, the implementation of budget splits has redistributed industry returns among channels and categories instead of affecting change on consumption patterns.

Regarding prescription behavior, the **system is not at the stage** to enable consistent assessment of clinical justification. **Prescription protocols are non-binding**, often outdated and typically developed without incorporating **reimbursement rationale**, limiting their impact.

At the same time, the system operates **without incentives for appropriate behavior or penalties for deviation**, resulting in **limited protocol adherence** and **variation in clinical practice**. **Audit mechanisms are weak or nonexistent** and prescribers receive **little feedback** on performance or prescribing outcomes.

Furthermore, **pharmacist remuneration through fixed margins** encourages dispensing **higher-cost therapies**, reinforcing inefficiencies at the point of execution. These gaps are reflected in the **prescription mix**, where **off-patent branded medicines are often favored over generics**, even when equally effective and more cost-efficient alternatives exist. Available data suggests that **this imbalance is not driven by excessive prescription volume, but rather by suboptimal mix.**

source: IOVE

Why it is important

Controlling pharmaceutical demand is **central to ensuring a more sustainable and equitable healthcare system**. Introducing transparent, structured prescription control mechanisms supports the broader goals of being patient-centric, fair, and efficient, which are principles that underpin the healthcare vision. Without addressing these issues, the system **cannot plan effectively, ensure optimal access to therapies or promote accountability**. In turn, this limits its ability to build trust, manage financing responsibly and meet population health needs in a predictable and data-driven manner.

Proposal's Rationale

The proposal aims to close the gap in prescription management through a **structured and phased implementation of control mechanisms**. It introduces the formulation of a prescription strategy per ATC, supported by validated protocols co-developed by EOPYY and scientific bodies. The integration of e-prescription and diagnostic tools will enhance compliance, while dedicated campaigns will improve awareness. Crucially, oversight mechanisms such as audits, benchmarking, and penalties will incentivize proper behavior and curb overspending. By anchoring **clinical decisions to both therapeutic outcomes and economic rationale** it then becomes feasible to **gradually move to a more simplified budget split**, in line with examined benchmarks.

Address Demand Holistically

The only way to effectively control demand is by implementing prescription protocols and by building control mechanisms that lead to corrective actions

Proposal conceptualization

Budget Structure	Protocol Drafting	Protocol Implementation	Awareness Increase	Supporting mechanisms
Budget re-structuring to two channels based on procurement mode (Hospital & Out-of-Hospital). Key design principles: – Convergence in industry returns (ex-factory prices) – Adequate financing for products not included in closed sub-budgets	– Formulation of approach per ATC and available treatment options by EOPYY & medical societies – Collaboration between EOPYY and medical societies (incl. Therapeutic Protocol Committees) for prescription protocols drafting	– Introduce new locked protocols in ATCs that are not currently in place – Expand e-prescription infrastructure for hospitals – Lock existing protocols through establishing links with EHRs, filters and e-prescription	– Targeted campaigns to inform on prescription alternatives and raise awareness – Implement a system (IT, processes, rewards) engaging HCPs and enabling them to propose amendments	– Cross-reference consumption and prescription data to track patient adherence to protocols – Establish monitoring mechanisms and safeguards to regulate prescription behavior

Supporting Mechanisms

Prescription validation: Establish network of CoEs (located inside dedicated hospitals) to validate & enforce higher scrutiny to prescription of high budget impact medication (incl. ones coming through IFET)

Quotas & benchmarking: Perform regular benchmarking per specialty, geography, ATC, legal basis etc. to draft baseline patterns and establish quotas

Audits & penalties: Develop audit mechanism that is triggered after deviation from baseline patterns & formulate penalties framework for HCPs that are deviating from protocols

Case Study Highlights

Budget structure

All countries examined budget around two channels based on purchasing modes or intended consumption pattern

Prescription protocols drafting

Prescription guidelines use a traffic light model to enhance adherence, offer flexibility, and include monitoring for the "dark-yellow" group.

Simplification of protocols system

Prescription guidelines use a traffic light model to enhance adherence, offer flexibility, and include monitoring for the "dark-yellow" group.

Auditing prescription behavior

Doctors exceeding benchmark volumes by over 25% are first consulted and repeated breaches require repayment of the excess.

Address Demand Holistically

Despite key factors such as HCP engagement and digital readiness, prescription protocols are expected to improve demand control and streamline access to treatment

Key Implementation Considerations

HCPs' Community Buy-in

Securing the engagement of the medical community and scientific associations is critical. Their involvement ensures smoother implementation and helps minimize resistance, especially in clinically sensitive areas.

Digital Capabilities

Full interoperability between the e-prescription system and healthcare IT platforms is essential. Real-time access to diagnostic results, patient data and consumption strengthens the reliability and practicality of protocols, and aids simplified budgets.

Reimbursement & Budget

Protocols should be embedded within the broader reimbursement framework. The Negotiation Committee and budget allocation mechanisms need to reflect the new prescribing approach and support discipline and predictability.

Gradual Implementation

Initial deployment should begin with selected therapeutic areas that represent high cost or high frequency. A phased national rollout allows for better control, continuous evaluation, and timely refinements to the budget structure.

Anticipated Impact

Increased Efficiency

The introduction of clear and standardized prescribing protocols is expected to significantly reduce unnecessary and inappropriate prescribing, improving the overall efficiency and effectiveness of pharmaceutical resource allocation.

Streamlined / Equal Patient Access

A uniform and transparent prescribing framework will help ensure that all patients, regardless of region, socioeconomic status or provider, have timely and fair access to appropriate, high-value treatments based on consistent clinical criteria.

Improved System's Predictability

Systematic and rule-based prescription controls will enable better forecasting of pharmaceutical needs, supporting more accurate budgeting, long-term planning, and clearer communication between the state and the industry.

Cultural Shift

The initiative will contribute to a more structured, responsible and accountable prescribing culture, where clinical autonomy is maintained but guided by shared, evidence-based standards and long-term sustainability goals.

Initial implementation timeline

6-12 months (pilot) / 12-36 months (full roll-out)

Unlock Data Potential

The data infrastructure is held back by low data quality and interoperability, limiting evidence-based policymaking and efficient care provisioning

Current State

Greece is currently developing multiple databases for primary and secondary health data usage such as the national EHR and oncology registry. As the health data infrastructure matures, data quality and interoperability become the main priorities for unlocking value through data that **saves patient lives and raises the system's efficiency**

Interoperability is inextricably linked with data quality since the **fragmentation of systems** contributes to the **overreliance on manual inputs** from HCPs and administrators, while cutting-edge tools that safeguard standardization of data (such as AI) are not leveraged meaningfully. Systems' interoperability is considered limited, as data collection, storage and processing is **fragmented, often by region**.

Another area for improvement in terms of data quality concerns **data input standardization**. There is currently a lapse in design that ensures data inputting follows a set of **protocols**, with **mechanisms to correct errors** and inconsistencies in a timely manner.

Finally, the current state of affairs concerning data leads to low utilization of health data for evidence-based **policy decisions**, since datasets that synthesize large amounts of data are seldom made available in a timely manner, while manual inputs create the risk of **systematized incorrect entries due to cultural factors**.

Why it is important

A robust health data ecosystem is crucial to **improving clinical outcomes and patient quality of life** by minimizing duplication of efforts and reducing avoidable errors in care delivery. Timely, accurate health data are essential for the proactive planning and real-time monitoring of health policies.

Importantly, data must be **accessible not only to public stakeholders but also to the industry**. In a system with elevated levels of industry returns, **manufacturers require better visibility to accurately forecast performance** and investment risk.

Proposal's Rationale

Given the breadth of ongoing infrastructure projects, the proposal focuses on **maximizing value from existing systems** through **better integration, interoperability and data use**. As such, the proposed initiatives are centered around securing that existing data can be leveraged fully to enhance **clinical excellence and operational efficiency** but also serve as a **strategic asset for broader system resilience and innovation**. Finally, it should be noted that proceeding with these initiatives is a key enabler for bridging the financing gap and monitoring the progress towards meeting the already discussed dual spending target.

Unlock Data Potential

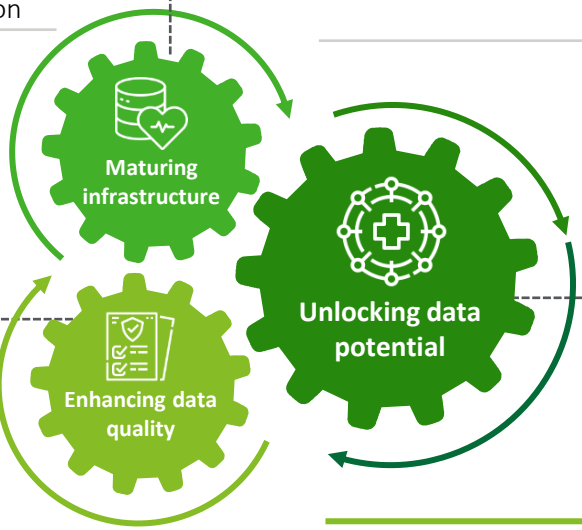
Moving from digital readiness to digital maturity is of paramount importance to unlock data utilization potential

Key recommendations

- Maintain current digitalization efforts, focusing on interconnecting systems
- Map current data flows and develop a metadata catalog
- Build interoperability bridges
- Perform comprehensive training programs for HCPs on utilization

Key recommendations

- Develop predictive models and tools, utilizing key consumption data, to enhance budgeting process
- Enable the real-time monitoring of newly introduced policy measures to assess impact
- Support EKAPY for faster and more accurate clawback notes calculation



Embedding data in forecasting & monitoring

Sharing the data with industry stakeholders

Key recommendations

- Establish specific input protocols and reward system to incentivize correct data input
- Leverage AI to conduct projects on increasing data quality (e.g., filling data gaps)
- Introduce automations and system's data transfers to minimize input requirements

Key recommendations

- Introduce yearly statistical reporting through publication of dedicated report on pharma
- Institutionalize monthly pharma bulletins containing key data & metrics

Case Study Highlights

Data Quality Enhancement

Utilization of AI models to extrapolate missing data from cancer registries and facilitate real-time updates to registries and databases

Digitally Mature System

Regional EHRs are centralized into national registries; implements national data input specifications and standards, alerting HCPs on errors and reporting to validate' data quality

System Monitoring and Triggers

When close to fixed budget limits, the system triggers budgetary controls, negotiations for price reductions and industry returns

Data Quality Enhancement

Publication of data maturity index assessing and benchmarking trusts – organizations while also including information and guidelines for HCPs (e.g., data input issues or common mistakes)

Unlock Data Potential

Enabling a data framework implies engaging multiple stakeholders, clarifying ownership and governance structures and investing in technologies and capabilities

Key Implementation Considerations

Multistakeholder Engagement

Data enhancement is by design a collaborative effort and requires engagement of multiple stakeholders, including PACs, HCPs and the pharmaceutical industry. Lack of coordination and alignment on the value of data can compromise benefits and usability.

Data Ownership & Governance

Clarification of any confusions over data ownership and establishment of clear governance framework on collection, storage and utilization. See the Enable Data Ecosystem proposal for more details on the proposed initiatives in this direction.

Advanced Digital Capabilities

The pace of recent technological progress necessitates understanding advanced digital capabilities (e.g., advanced modelling) to properly leverage and maximize the benefits from digitalization efforts and data production.

Investments in Technology

Ensuring adequate data gathering capabilities across the system (incl. regional units) and selective investments in technologies with high anticipated impact is essential to avoid discrepancies and support evidence-based decision-making at a national level.

Anticipated Impact

Enabling Pharma Policy

By establishing a robust data infrastructure and the respective evidence-based processes, the state can have a solid base to enable broader pharmaceutical / healthcare policy drafting, reducing reliance on ad hoc actions and fostering long-term sustainability.

Increased Efficiency & Monitoring

Data availability and integration in decision-making is expected to drive increased efficiency in the broader system and improve the state's monitoring capabilities (incl. impact of specific policies), enabling timely adjustments and better resource allocation.

Trust Enhancement

Data sharing and establishing a single version of truth (data-based) regarding the system's financing will improve stakeholders' trust and increase overall system transparency, reducing misalignments and facilitating more constructive collaboration.

Business Ecosystem Improvement

Increased transparency in the system and data sharing with the industry will improve the pharmaceutical business environment and elevate Greece as an investment destination, attracting innovation and strengthening the system's quality.

Initial implementation timeline

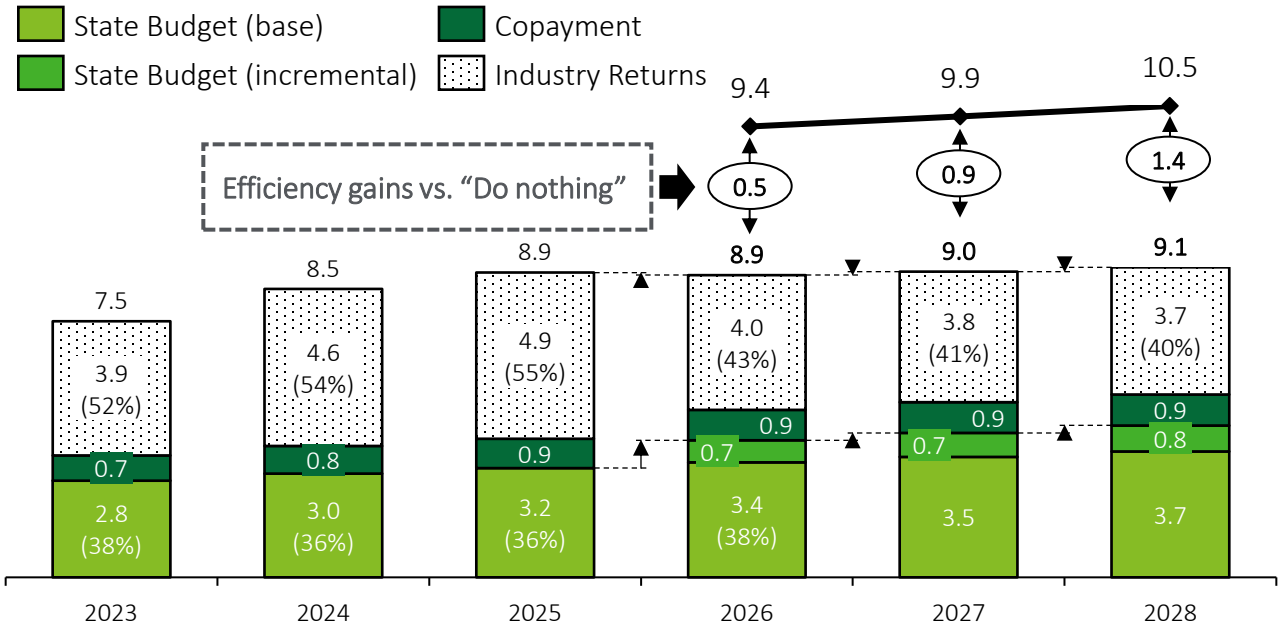
12-18 months

Estimating Proposals' Budget Impact

The implementation of the proposed initiatives can potentially reduce pharmaceutical spending by ~€1.4b, accompanied by a ~€0.8b increase in public financing

Roadmap pillars	Impact lever description	Budget impact on maturity (2028)
Secure adequate financing	Deactivation of inactive SSN's & uninsured spending via social affairs	Public Financing Increase: €220m – €260m Total Financing Decrease: €100m – €120m
	Budgeting for protection measures overflow	Public Financing Increase: €100m – €140m
	Budgeting for indirect cost of preventative screenings	Public Financing Increase: €230m – €270m
	Establishment & financing of Innovation Fund	Public Financing Increase: €130m – €170m
	Enhanced monitoring and scrutiny over IFET's operations	Total Financing Decrease: €180m – €220m
Manage demand holistically	Introduction of new locked protocols & linking of existing ones	Total Financing Decrease: €330m – €420m
	E-prescription roll-out to hospitals	Total Financing Decrease: €370m – €480m
	Monitoring of HCP prescription patterns	Total Financing Decrease: €250m – €300m
Unlock data potential, as an enabler		

Figure 16. Preliminary Budget Impact, in €m



Note: See Appendix III for detailed budget impact assumptions
Source: SFEE Projections

Note: The range of values for individual budget impact assumptions result from assuming a 10% range after analysis presented in Appendix III, while their median value is used to arrive at target state for total spending, presented in Figure 16

Transforming the System

Enable Data Ecosystem

European Health Data Space provides a great opportunity for the country to make the leap-frog and drive value creation through extensive secondary data use

Current State

The upcoming establishment of the **EHDS provides a significant opportunity for Greece to modernize its health data governance** and capitalize on its emerging digital capabilities. As digitalization steadily advances, **investments in infrastructure and electronic registries are beginning to improve data availability, granularity** and **timeliness**.

To fully unlock this potential, Greece must now focus on building an integrated data ecosystem—one that includes **central governance mechanisms, clear access frameworks and a common technical architecture** across all healthcare stakeholders. This would not only ensure **alignment with European standards** but also create the **basis for a structured and secure secondary use of data**. Importantly, doing so **could establish a new revenue stream for the system**, as structured health data becomes a valuable asset for research, innovation, and strategic planning.

A major contributor to the **current underutilization** of health data remains the **fragmentation of information systems**, coupled with limited interoperability and non-standardized input protocols. These issues **reduce both data quantity and quality**, inherently lowering its value. Additionally, multiple public entities, such as EOPYY, EKAPY and IDIKA, hold data across different segments of care, without a unified access or governance model, further complicating structured and timely data use.

Why it is important

Leveraging the opportunity that EHDS presents and building a **centralized data access hub** is essential for building **a modern, transparent, and investment-ready healthcare system**.

A streamlined, accessible health data ecosystem is a **critical enabler of innovation**. For pharmaceutical and life sciences companies, access to robust real-world data (RWD) is a key factor in investment decisions Greece risks missing out on opportunities to position itself as a **hub for research and digital health development**, as well as leveraging **potential revenue streams** from providing value to the ecosystem.

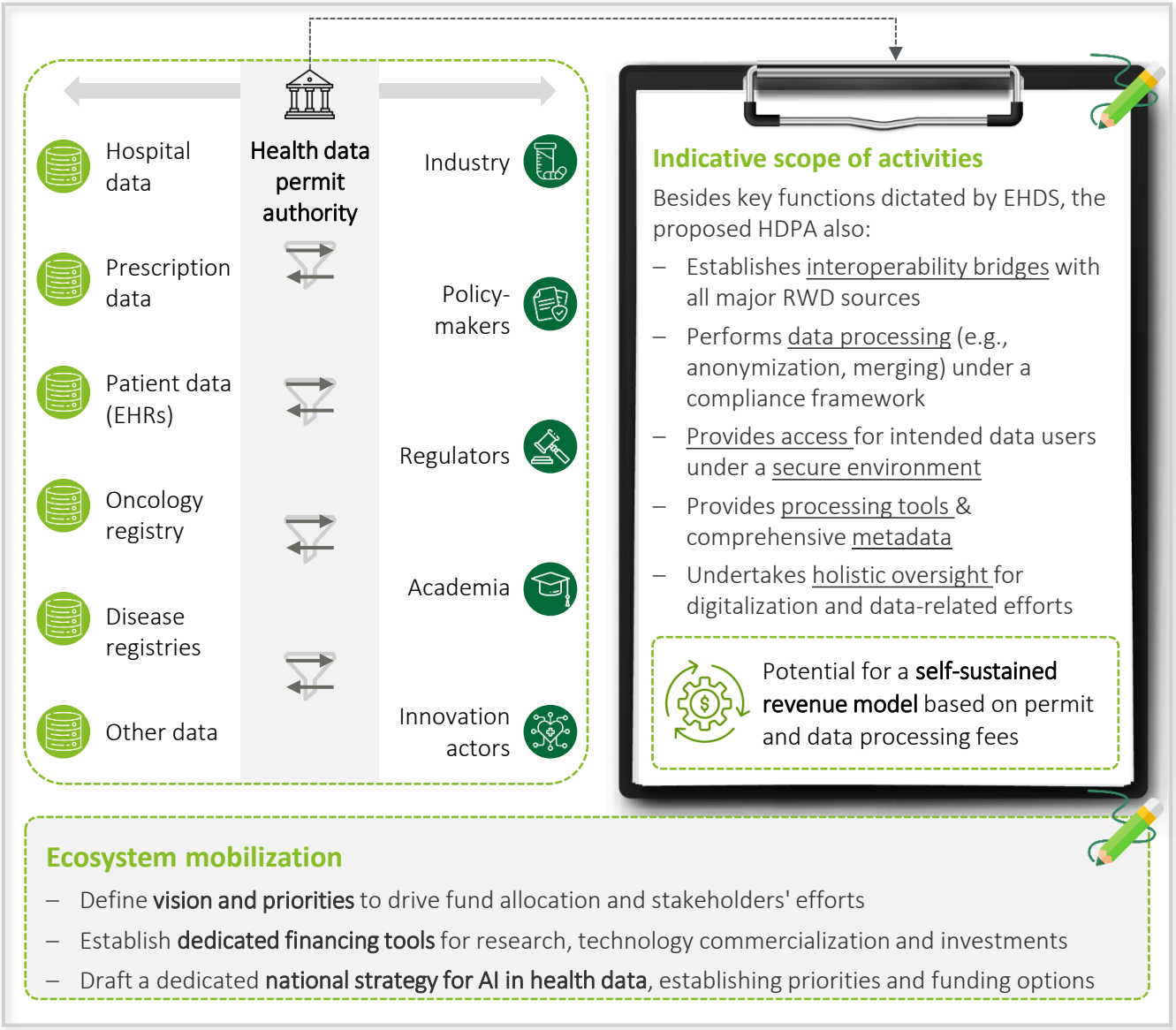
Proposal's Rationale

The proposal aims to define characteristics of a **HDPA body** that will maximize the value of Greek health data by ensuring as many stakeholders as possible can gain access to RWD for legitimate purposes. To accomplish this, the HDPA should have a **one-stop-shop role,** providing the **necessary tools and regulatory support** to assist SMEs, innovative companies and small research teams in **creating value to the health ecosystem through data.**

Enable Data Ecosystem

Setting a robust data framework by introducing a Health Data Permit Authority with extended scope and role is expected to unlock significant value for the entire ecosystem

Proposal conceptualization



Case Study Highlights

Health Data Permit Authorities

Findata provides access to a broad array of data and advanced research and processing tools, including pre-processed data, under a fee-for-service revenue scheme

The French HDPA provides a holistic access framework while also providing research grants provisions & release of specific data challenges with monetary prizes

Spain was part of the EHDS2Pilot, aiming to define and build a common IT infrastructure and common standards, metadata catalogs, data quality and interoperability, while has also legislated the respective framework and documented acceptable use cases

Enable Data Ecosystem

A national permit authority must standardize secure, structured access and processing in line with EHDS, enabling evidence-based decision-making

Key Implementation Considerations

Technical Onboarding

Deployment of a data access platform that links hospital, EHR and registry systems via EHDS-compliant APIs, using data standards to enable secure, structured integration of data systems which are often provided by different vendors.

Permit Workflow

Definition of structured permit workflows and anonymization requirements, including screening for applications, thoughtful usage rules and audit mechanisms to streamline access while safeguarding data privacy.

System & Human Capabilities

Development of digital tools and upskilling programs for data users and permit authority staff to ensure secure and consistent data access, processing and remaining up to date with industry and research modus operandi.

Monitoring System

Establishment of audit mechanisms and real-time monitoring tools to ensure compliant data use, detect misuse, and maintain transparency within the permit authority.

Anticipated Impact

Data-driven Policy-making

The structured secondary use of real-world data enables smarter planning, targeted interventions, and evidence-based resource allocation across all levels of the health system.

Enhanced HTA Capabilities

Use of structured data supports dynamic HTA processes, horizon scanning, post-launch monitoring, and value-based pricing models tailored to real-world performance. Aligning with EU HTA will raise the bar even further in terms of data usage requirements.

Research & Innovation

Direct access to real-world data reduces duplication, shortens timelines, and enables studies that reflect actual patient populations, treatment pathways, and system needs.

Sustainable Funding Pathway

Fee-based services for permits and data handling can support the long-term operation of the system, ensuring sustainability without exclusive dependence on public budgets.

Initial implementation timeline

12 months (design) / 12-36 months (Implementation)

Israel Case Study – Data Ecosystem Fundamentals

Israel is a global leader in digital health, known for its advanced data collection and long-standing use of digitized medical records that drive innovation and improve patient care

National Digital Health plan

Ministry of Health

- Regulates data access, privacy, and interoperability standards
- Oversees HIE infrastructure and approves secondary use frameworks

Initial investment of ~$260m for digital infrastructure & regulatory reforms

HMOs	Hospitals	Research Institutions / Academia	Advanced Research Databases
EHRs and prescription data	*Clinical and inpatient data*	*Proprietary & statistical data*	*Big data (Tamma system)*

Health Information Exchange platform

EITAN is Israel's national health data exchange platform, run by the Ministry of Health, using a decentralized architecture to securely share clinical data in real time across providers

Key characteristics

- *Ownership Model*: each healthcare organization retains full ownership and control over the clinical data it generates
- *Decentralized Control*: EITAN does not store patient data centrally. Instead, it enables data exchange through a federated model, where data remains within local systems and is shared only upon request and authorization
- *Selective Sharing*: Participation in the exchange requires mutual agreement. Organizations decide what data to expose and under what conditions. No data is automatically centralized

Implementation Design

No use of a central database

Decentralized approach in storing medical data for enhanced security and greater stakeholder acceptance (incl. patients' resistance)

Ensured security standards

All data transfers and inter-organizational connections must comply with Israeli security and privacy regulations, as well as international standards like HIPAA, GDPR, and ISO

Provision of data at time of care only

Israel enhances medical data security by allowing access only to authorized healthcare professionals at the time of care, ensuring that data is shared for specific purposes, with limited scope and duration

Private sector know-how utilization

Indirect access through government-approved research collaborations and secure sandbox environments managed RWD providers and dedicated platforms such as TIMNA and Lynx MD

Source: Government of Israel, ICLG - Digital Health Laws and Regulations – Israel, The Implementation of a National Health Information Exchange Platform in Israel

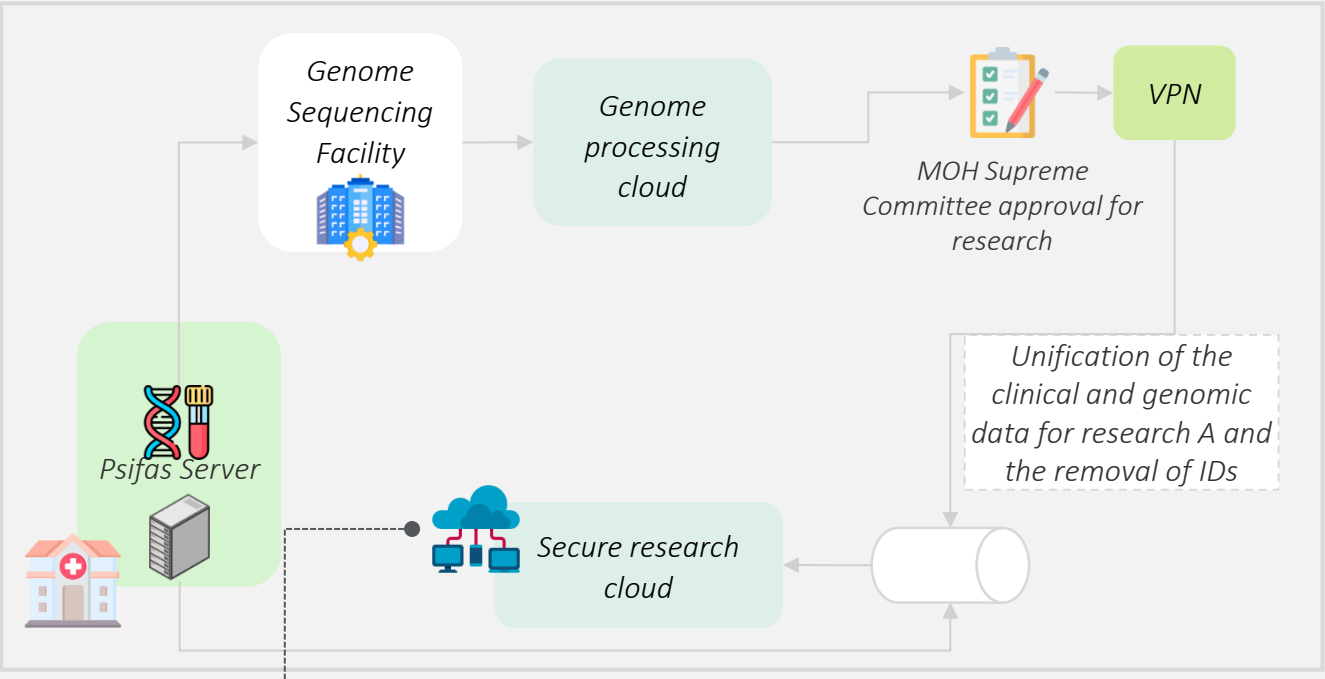
Israel Case Study – Sharing Data With Academia

Academia plays a leading role in health innovation, with the Mosaic initiative showcasing collaboration with the state to integrate genomic and clinical data for research

The Mosaic Initiative

A national program, launched in 2023, aimed at building a national infrastructure for personalized medicine by integrating genomic sequencing with long-term clinical data from health organizations

Led jointly by government and top academic institutions like Weizmann and Bar-Ilan, forming a strategic alliance with hospitals and HMOs



Universities use the genomic-clinical data to develop AI tools, support drug trials, and advance disease-specific research

Financing Evidence-based Research

Magnet

- Supports generic infrastructure tech development in areas where Israeli industry has or can build a global competitive advantage
- Enables cooperation between academia and industry, facilitating knowledge sharing and joint R&D
- Offers up to 100% funding for academics, 66% for companies, depending on consortium type

Magneton

- Promotes technology transfer from academic institutions to industry via mutual cooperation between an industrial company and an academic research group
- Provides up to 66% of the approved budget, with the research institute owning the knowledge and acting as a full partner—not a subcontractor

NOFAR

Supports applied academic research in biotechnology and nanotechnology that is not yet mature enough for industry investment or the MAGNETON program

Source: ICPerMed, Bar-Ilan University, Israel Innovation Authority

Introduce Collaborative Platform

Pharma policymaking in Greece remains fragmented and informal, lacking a structured framework for stakeholders' coordination and alignment on long-term system priorities

Current State

Pharmaceutical policy planning in Greece **lacks an institutionalized framework** that enables consistent and effective stakeholder engagement. **Input from key actors**, including health authorities, scientific committees and the pharmaceutical industry, is currently **fragmented, ad hoc,** and in some cases **informal**. This results in an absence of collective ownership, weakening both coordination and follow-through on strategic priorities.

Moreover, there is **no permanent structure to facilitate policy dialogue**, **align agendas** or monitor **implementation of system-wide initiatives**. In practice, **policy is formulated in silos**, with limited visibility, short planning horizons and **minimal continuity between successive initiatives or leadership cycles**.

Expert and reimbursement committees operate in isolation, often without mechanisms to communicate or synchronize with broader health planning. There is **no integrated governance model** to link their decisions with wider system goals such as innovation adoption, access equity, or budget sustainability.

Lastly, **proposals related to investments, pricing reforms or innovation access** are usually **considered only after issues become pressing**, rather than through a proactive, strategic process. The **absence of transparent procedures and structured prioritization criteria leads to delays**, inconsistencies, and growing frustration across the ecosystem.

Why it is important

Institutionalizing stakeholder input is essential to ensure **more transparent, coordinated and evidence-informed pharmaceutical policymaking**. A national council strengthens public-private collaboration, improves alignment on priorities and builds trust across the ecosystem.

It also enables **structured discussions on long-term planning and investment**, promoting continuity, reducing fragmentation and supporting more strategic and accountable policy development.

Proposal's Rationale

Establishing a national pharmaceutical council introduces a **formal advisory body with broad representation**, **regular policy dialogue** and **taskforces focused on key priorities**.

It connects existing expert committees, creates a centralized platform for investment discussion and strengthens coordination between state and industry.

This structure **enhances transparency, enables faster alignment** and provides a **sustainable mechanism** to support strategic health system goals.

Introduce Collaborative Platform

Establishing an empowered national pharmaceutical council can enhance state–industry collaboration, guide policy design and strengthen transparency in decision-making

Proposal conceptualization

Introducing National Pharma Council

Governance structure	General Oversight: MoH Presidency: GS of Strategic Planning
Indicative participants	State officials (incl. EOPYY, HTA, NC, EKAPY & HDPA / IDIKA), industry representatives
Role in the ecosystem	Primarily advisory body (not mandatory in implementation)

Scope of activities

Advise on Policy Formulation

- Formulates proposals for targeted policies
- Monitors and assess impact of current policy framework and proposes amendments

Information Sharing

- Creation & oversight of financial data platform (link to KMES)
- Industry to share input regarding financing projections & budgeting

Project Facilitation

Formulation and oversight of taskforces with specific assignments (e.g., digitalization, clinical trials, public health initiatives)

Key Mechanics

Institutionalized touch-points to discuss in advance expected legislative actions or regulatory changes

Established dialogue forums for all relevant stakeholders to express their PoVs & bring issues

Projects sponsorship by industry participants

Case Study Highlights

National Life Science Council

An advisory council composed of ecosystem stakeholders supports the central government on pharma strategy. Key areas include clinical trials regulation, financing mechanisms for scale-ups, partnerships with public health providers, legal framework for data use, and manufacturing licensing processes.

National pharmaceutical strategy

Inter-ministerial coordination structures jointly involve the industry in shaping and monitoring the national pharmaceutical strategy. A dedicated forum aligns public and private stakeholders on common priorities, while public-private R&D initiatives promote coordinated investment, infrastructure, and innovation.

Introduce Collaborative Platform

Establishing a national council can formalize regular input from key actors, unify expert committees under coordinated governance and enable policy dialogue

Key Implementation Considerations

Composition and Mandate

The council will define a structured governance framework, including stakeholder group representation, voting/advisory roles and decision-making mandates. This ensures a stable and legitimate platform for ongoing pharma policy input.

Collaboration via Taskforces

Existing expert committees (e.g. pricing, HTA, monitoring) will be integrated into dedicated taskforces operating under the council's umbrella.

Investment Submission Platform

A digital space will be created where companies can submit structured investment proposals. Authorities will provide timely feedback on alignment with national priorities, relevance, and timing, facilitating early engagement and more strategic planning.

Dual-purpose Taskforce Model

Taskforces will serve two roles: provide continuous expert input for pharmaceutical strategy and act on an ad hoc basis to assess specific submissions or policy proposals. This model ensures both long-term consistency and short-term responsiveness.

Anticipated Impact

Collaboration Among Stakeholders

The council will institutionalize dialogue between government and stakeholders, enabling structured, regular engagement in pharmaceutical policymaking and reinforcing alignment over time.

Informed Decision-making

Frequent expert input and stakeholder dialogue will lead to more balanced, data-driven, and technically sound decisions across areas like pricing, reimbursement and innovation funding.

Transparency & Predictability

Planning processes and policy intentions become clearer through structured engagement. This reduces uncertainty for all actors and enables better forecasting and policy coordination.

Catalyst for Cross-sector Initiatives

The council can act as a launchpad for broader policy efforts such as data-sharing pilots, joint HTA initiatives or coordination on digital and infrastructure tools that support access and innovation.

Initial implementation timeline

6 months (design) / 6-12 months (implementation)

Reform HTA

The Greek HTA process is relatively rigid and narrow in scope underplaying the long-term value medicines bring

Current State

The current state of **HTA** for medicines in Greece reflects a **system still in transition**, facing both structural and methodological limitations. Entry into the HTA process is gated by a **series of eligibility filters,** most notably the "5/11 rule", which requires that a medicine be reimbursed in at least 5 of 11 designated countries that engage in HTAs. This significantly narrows the scope of medicines that even reach the HTA stage, contributing to delayed access to innovative therapies, especially for rare or orphan diseases.

Once a medicine qualifies, **the evaluation itself does not consider clinical benefit in a holistic sense**, such as a medicine's long-term value to the health system and society. Another major issue is **the expanded role assumed by the HTA committee, which complements reimbursement authorities**. This situation has significant efficiency and quality assurance implications, leading to delays in the reimbursement decision step of the market access process.

Looking ahead, Greece is expected to align its HTA procedures with the European Union's evolving regulation on joint clinical assessments. While this is a positive step toward increased consistency and quality, the national framework will need to evolve accordingly to ensure timely adoption, integration with pricing decisions, and improved access to high-value treatments.

Why it is important

Improving the HTA process in Greece is essential for building a **forward-looking**, **value-focused** health system that ensures **timely and equitable access to effective medicines**. The current limitations undermine the system's ability to make decisions based on the full value a treatment offers to patients, the health system, and society at large.

A reformed HTA process must go beyond short-term cost containment and instead **evaluate long-term outcomes**, such as reduced hospitalizations, improved quality of life, and economy-wide productivity**.**

Proposal's Rationale

The proposal includes **two sets of initiatives**. The first set aims to ensure that **Greece fully leverages the upcoming EU-level HTA reform**, not only by adopting joint clinical assessment outputs, but also by **enhancing national readiness to integrate and operationalize** them effectively. This involves addressing regulatory, legal and process-level prerequisites to secure timely uptake and maximize the strategic value of the EU-wide framework.

The second set of initiatives propose a new direction for **how HTA output is assessed in the negotiation and reimbursement processes**. Focused on linking clinical benefit to value and cost-effectiveness, the proposed direction will contribute to delivering a more efficient system.

Reform HTA

Adapting Greek HTA assessments to EU HTA can create value through a reformed operating model and increased engagement with EU peers & centralized authorities

Proposal conceptualization

Abolition of 5/11 rule given EU implementation law that constitutes the measure redundant

Leverage EU HTA to streamline assessments

- **Adopt good practices** identified from recent knowledge exchange programs and technical support from EU programs
- Implement **legal, regulatory and infrastructure interventions** necessary for alignment with EU HTA
- Ensure readiness to create value from **increased participation** in EU processes (JCA, PICO scope)

- Proceed with establishing a **separate HTA body**, a clear **governance** framework and definition of **stakeholder engagement** mechanics, incl. consultations with MAHs
- Re-frame **cost-effectiveness approach** following renowned methodologies
- Establish a **fast-track appraisal mechanism**, linked to dedicated innovation pathway
- Launch and actively manage a **horizon scanning platform** (in collaboration with the industry)

Re-orient Greek HTA towards capturing value

The purpose of the proposed initiatives is to complement current efforts on alignment with EU HTA requirements

Case Study Highlights

Clinical Assessment

SMR rating

Disease severity and therapeutic strategy considering treatment line and comparators

ASMR rating

Improvement versus existing options, also influences prescribing decisions

Combination leads to prescription line placement and drives corresponding reimbursement rate

Horizon Scanning – Pharmascan

An online database with regulatory, clinical trial and budget impact data on new medicines. Provides information to the entire ecosystem . Key intended uses include:

- Pathway and system planning
- Identifying candidates for accelerated access
- Development of HTA schedules
- Production of briefings/ information dashboards
- Local planning (formulary, care design, budgeting)

Reform HTA

Reforming the national HTA can improve the quality and consistency of access decisions, strengthen prioritization of value, and enable more efficient use of resources

Key Implementation Considerations

Assessment Methodology

Definition of the most appropriate value assessment approach, leveraging successful practices from comparable EU countries while ensuring applicability in the Greek context.

Capacity Building for HTA Experts

Training and technical support to align evaluators with updated methodologies, value frameworks, and European standards, ensuring consistent and high-quality assessments.

Horizon Scanning Operating Model

Definition of the overall system setup, including governance structures, technological infrastructure, and coordination mechanisms with key stakeholders across the healthcare ecosystem to promote readiness to assess future innovation.

Performance Monitoring System

Establishment of indicators and reporting tools to monitor HTA process timelines, quality of assessments, and adherence to EU-aligned standards and best practices, securing the assessment framework continually provides desirable results.

Anticipated Impact

Access to Therapies

HTA-driven decisions help systematically prioritize treatments with demonstrated added value, thereby improving equity in access and minimizing reimbursement of products with limited clinical benefit.

Value-based Budget Allocation

Systematic assessment of clinical and economic benefit—linked with the Negotiation Committee—supports value-based prioritization and minimizes inefficient spending.

Improved Decision Speed & Quality

Structured evaluation processes combined with early visibility into the pharmaceutical pipeline contribute to reducing procedural delays, ultimately enabling faster access to high-priority and high-impact therapies.

Stronger Incentives for Innovation

HTA processes that explicitly recognize and reward both clinical and technological innovation enhance the attractiveness of launching high-value products in Greece, while also reinforcing the country's position as a destination for investment in transformative R&D.

Initial implementation timeline

6 months (design) / 6-24 months (implementation)

Promote Value-based Negotiations

Pricing decisions remain focused on upfront cost, without factoring in real-world performance, budget impact or long-term system benefits

Current State

The Greek negotiation framework remains largely centered on cost, **without** an integrated approach to assessing **therapeutic value, budget impact or real-world outcomes**. Negotiations are focused primarily on **upfront cost**, rather than aligning price with actual performance or long-term system benefits.

Currently, **there is no consistent methodology** for evaluating the broader impact of new medicines on patient health, hospital use or public budgets. Innovative therapies are assessed in isolation and **pricing decisions are rarely linked to clinical need, health system efficiency or societal value**.

In addition, **real-world evidence (RWE) is not systematically incorporated** into reimbursement or pricing discussions. This limits the ability to reflect how medicines perform in practice and **prevents dynamic adjustments** as new evidence becomes available.

Finally, there is **no mechanism to account for cost-avoidance**, such as reduced hospitalizations or fewer complications due to treatment. The absence of this link leads to **fragmented budgeting**, reduced planning visibility and missed opportunities to reward therapies that generate long-term savings.

Why it is important

Strengthening the Negotiation framework is essential to make the system more **patient-centric, holistic** and **focused on value**. A modernized approach can ensure that resources are channeled toward treatments with proven real-world benefit, driving better outcomes for patients.

By incorporating **data-driven insights** and aligning with broader budget goals, the negotiation process becomes **more transparent and predictable**, supports smarter investment decisions, and enables faster access to meaningful innovation. At the same time, it enhances **equity**.

Proposal's Rationale

The initiative promotes a shift toward structured **value-based negotiations**, broadening the negotiation process beyond pricing. It introduces new components such as **cost-avoidance tracking, integration of RWE** and the use of a wider **economic impact framework**, including innovation as a key input.

It also empowers the negotiation body through expanded mandate and scope, including representation from the Ministry of Finance to improve **cross-budget coordination**. Together with robust MEAs, this approach supports more transparent, fair and sustainable pricing decisions.

Promote Value-based Negotiations

Empowering the Negotiation Committee by expanding its scope and capabilities is expected to better drive value creation across the system and fair allocation of burdens

Proposal conceptualization

Review composition

Include a **representative** from the **Ministry of Finance** to increase committee's **visibility** to other **healthcare budgets** and potentially **draft links** between consumption patterns across healthcare

Align negotiations to strategy

Repurpose negotiation premise on **net price**, based on **reimbursement strategy** & intended **prescription line**, and focus on the value addition by broadening the **economic impact methodology,** while introducing **innovation as a key value component**

Recognize cost-avoidance

Establish link with other **healthcare budgets** (primarily inpatient care) in order to recognize **cost-avoidance of innovative therapies vs hospitalization** & create respective financing mechanism *(premise could be tested through innovation fund implementation)*

Integrate RWE in the process

Implement necessary reforms for the usage of **RWE** (including joint clinical assessment output from EU HTA) in **decision-making** and internal analyses to better inform negotiations and define **expected value** for candidate drugs

Introducing Managed Entry Agreements

- Proceed with the necessary legal / regulatory actions to enable MEAs following good practices
- Define key required data points, collection capabilities and monitoring mechanisms to support MEAs

Case Study Highlights

Holistic negotiation premise

Economic assessment based on:

- Health and medical perspective (also taking into account non-pharma costs like hospitalizations)
- Socio-economic perspective (aiming to capture non-health system effects such as productivity loss etc.)

At the same time, NC is conducting supplementary analysis to predict long-term effects

Framework enabling risk sharing tools

Belgium has established the foundations for utilizing risk-sharing tools, robust primary RWD data collection (incl. disease registries, e-prescription, insurance databases) , centralization of data for secondary use (Knowledge Center) and a clear legal framework for clinical trials, and allow for increased penetration of MEAs

Promote Value-based Negotiations

Promoting value-based negotiations requires strong data systems and effective outcome tracking to support impactful pricing decisions

Key Implementation Considerations

Data Infrastructure

Upgrade and connect fragmented data systems to create a unified, interoperable infrastructure which will transform inconsistent clinical and cost data into reliable inputs that can be used during pricing negotiations and policy decisions.

Cost-effectiveness Methodology

Develop a comprehensive framework to evaluate the value of new medicines, based on clinical benefit, unmet need, cost-effectiveness, budget impact and societal outcomes, ensuring pricing reflects overall system priorities.

Cost-avoidance Monitoring

Introduce structured tools and protocols to track post-agreement savings, focusing on how treatments reduce future healthcare costs, such as avoided hospitalizations or complications.

Operationalization of MEAs

Define standardized processes, contract formats, and monitoring requirements to scale up risk-sharing and outcome-based agreements, enabling broader use of value-based pricing.

Anticipated Impact

Improved Public Spending targeting

Value-based agreements help concentrate resources on therapies that offer the highest clinical benefit, avoiding waste and supporting long-term sustainability.

Price Linked to Outcomes

By linking reimbursement to outcomes, pricing decisions better reflect the actual benefit patients receive in daily clinical practice, rather than relying solely on theoretical or trial-based efficacy claims.

Trust Among all Counterparties

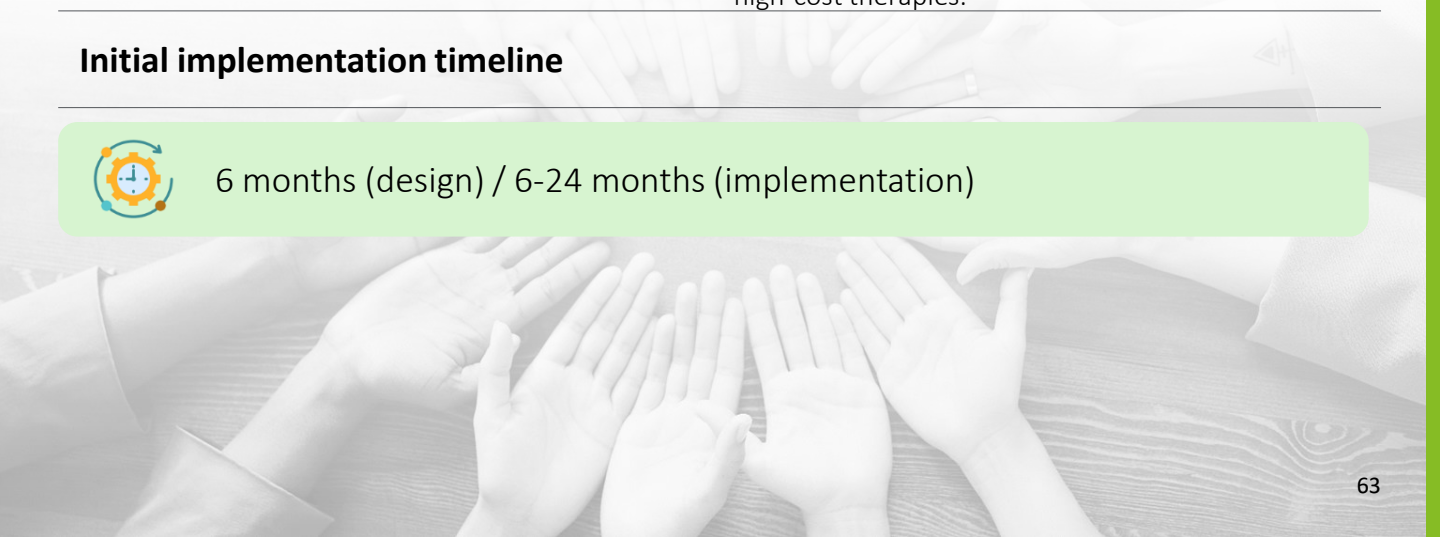
Using transparent and evidence-based assessment criteria improves accountability and credibility during negotiations, encouraging cooperation between public authorities, industry and other stakeholders.

Attractiveness for Market Entry

A well-defined value-based pricing framework offers predictability and clarity to pharmaceutical companies, reducing uncertainty and making Greece a more appealing market for launching innovative or high-cost therapies.

Initial implementation timeline

6 months (design) / 6-24 months (implementation)



Rethink Reimbursement Framework

The current reimbursement framework lacks prioritization, calling for a structured, value-based approach to improve value and access

Current State

The reimbursement process lacks a formal mechanism for prioritization, regular reassessments and updates based on evolving therapeutic needs. **Once a product is reimbursed, its value is rarely revisited**, even if newer clinical data or therapeutic alternatives emerge. In addition, **the list is not published on a regular basis and lacks a digitized platform for navigation**, reducing transparency and limiting access.

Reimbursement rates often vary significantly across comparable therapies, reflecting differences in handling that are not always linked to transparent or consistent evaluation criteria. Reassessment cycles may also be necessary to examine potentially outdated or low-value treatments that may continue to be prescribed.

This inefficiency also affects co-payment structures, as similar therapeutic options often subject to varying patient contributions. This **lack of consistency creates disparities in out-of-pocket costs** that are not necessarily linked to clinical value or therapeutic outcome.

The list also lacks **integration with system-wide budget planning**. Products are added without fully accounting for fiscal impact, which limits the ability to redirect funds toward higher-value treatments. **Clinical benefit is not systematically weighed against financial considerations**, creating inefficiencies and missed opportunities for more targeted coverage.

Why it is important

Reorienting the reimbursement framework for value is essential to **enhance system sustainability and promote rational reimbursement**. A structured and evidence-based positive list improves budget control and ensures funding is directed toward treatments with meaningful health benefits.

Incorporating **reassessment mechanisms, therapeutic mapping and updated co-payment logic** allows the system to respond dynamically to new evidence, usage patterns, and financial pressures. This also contributes to **fairer cost-sharing for patients**, supporting better access and efficiency.

Proposal's Rationale

The proposal introduces a **collaborative approach to rationalizing inclusion criteria**, reimbursement rates and co-payment policies. By embedding **therapeutic need mapping** and reassessment cycles, the list becomes a dynamic tool that reflects clinical priorities and promotes fairer cost-sharing. The approach increases transparency and ensures more strategic, data-driven pharmaceutical spending.

Rethink Reimbursement Framework

A collaborative project that aims to examine the reimbursement process, reviewing key concepts such as reimbursement criteria and reimbursement rates

Proposal conceptualization

About the project

A collaborative multi-stakeholder project aiming to introduce key design principles that address paradoxes and ensure a lasting impact and sustainability of reimbursement framework

Key project objectives

- Maximize clinical benefit of the collective products that are included in the positive list
- Ensure efficiency in resource allocation by identifying waste in reimbursement system
- Increase equitable access to the right treatments (covered at reasonable reimbursement rates)

Key focus areas

Inclusion criteria	*Number of generics per molecule, clinical / economical impact etc.*
Pricing & reimbursement framework	*Reimbursement rates, re-assessments, re-pricing*
Co-payment	*Rates & rationale (e.g., diagnosis based, income based)*

Design principles *(post-implementation)*

Ensure generics have a lower reimbursement rate vs respective off-patent product (enabling fiscal space for innovative and costlier products)

Publish the positive list quarterly and digitize its format

Maintain fair co-payment levels (even though changes will materialize during implementation, overall amount should not surpass today's)

Maintain a manageable number of products per ATC

Case Study Highlights

Reassessment frameworks

Reassesses each medicine's benefit and reimbursement every 5 years or upon significant new data, with decisions published in a standard format per substance

Reimbursement requires a 2-year price agreement, subject to renegotiation if new data shows high budget impact, overprescribing or poor cost-effectiveness

Co-payment schemes

Scale based on income with a maximum copayment
60% for high-income earners
50% for most incomes

Scale based on disease severity
100% coverage for vital
50%-85% depending on severity

Rethink Reimbursement Framework

The reimbursement framework must be reorganized based on structured prioritization, mapping of therapeutic needs and dynamic assessment mechanisms

Key Implementation Considerations

Multi-stakeholder Engagement

Establish a structured and inclusive collaboration framework involving national authorities, clinical experts and industry stakeholders. This joint process will be responsible for co-defining prioritization criteria and ensuring consensus-driven governance.

Treatment Needs

Conduct a comprehensive mapping of therapeutic needs by ATC classification to inform prioritization of reimbursed products. This will help phase out redundant or low-value treatments and ensure that the list reflects actual population health needs.

Assessment Mechanisms

Develop and institutionalize assessment and reassessment cycles for the positive list, activated by data on prescription trends, cost burden or newly available clinical evidence.

Anticipated Impact

Refocused Reimbursement

The positive list will evolve from a static product catalogue into a strategic reimbursement tool, aligned with therapeutic value and national priorities. This shift is expected to rationalize resource allocation and enhance overall system impact.

Fairer Distribution

Through redefined co-payment rules and evidence-based prioritization, access to reimbursed medicines becomes more equitable. Patients will face costs that better reflect both medical need and the intrinsic value of the products they use.

Predictable System Dynamics

The introduction of regular assessments and therapeutic benchmarks reduces reliance on ad hoc decisions. It strengthens long-term planning in reimbursement policy, enhances consistency and promotes data-informed governance.

Initial implementation timeline

12 months (design) / 12-30 months (implementation)

Broadening the Perspective

Strengthening Primary Care

Primary care in Greece lacks an effective gatekeeping role, leading to fragmented care, uneven access and unnecessary specialist use

Current State

Primary healthcare in Greece plays a **limited role as the structured entry point** to the health system. In practice, **patients often bypass general practitioners** and seek direct access to specialists, without undergoing triage or clinical prioritization. This results in **fragmented patient journeys**, inconsistent prescription patterns and overutilization of higher-cost secondary or tertiary services, even for cases that could be effectively managed at the primary care level.

The infrastructure supporting primary healthcare also remains **uneven and under-resourced**, particularly in rural or remote areas. **Digital tools, data integration and clinical support systems** to assist general practitioners with triage decisions, referral protocols and prescription responsibility are either limited or absent.

Furthermore, **cultural norms and patient habits** have traditionally favored specialist consultations, reinforcing a demand-driven use of care. Simultaneously, **primary care providers face limited incentives** to take on formal gatekeeping responsibilities, while workforce shortages and the absence of career development paths further constrain GP coverage and capacity.

Why it is important

A strong gatekeeping model is essential to ensure the system becomes **more patient-centric, holistic and focused on value**. By guiding patients through structured care pathways, the system can deliver **appropriate treatment at the right time**, improving disease management and long-term outcomes.

Empowering primary care creates a **more balanced, equitable and efficient health system**, allowing for better planning of resources and pharmaceutical budgets. A **holistic, GP-centered model** improves prevention, treatment continuity and fosters trust between patients and healthcare providers.

Proposal's Rationale

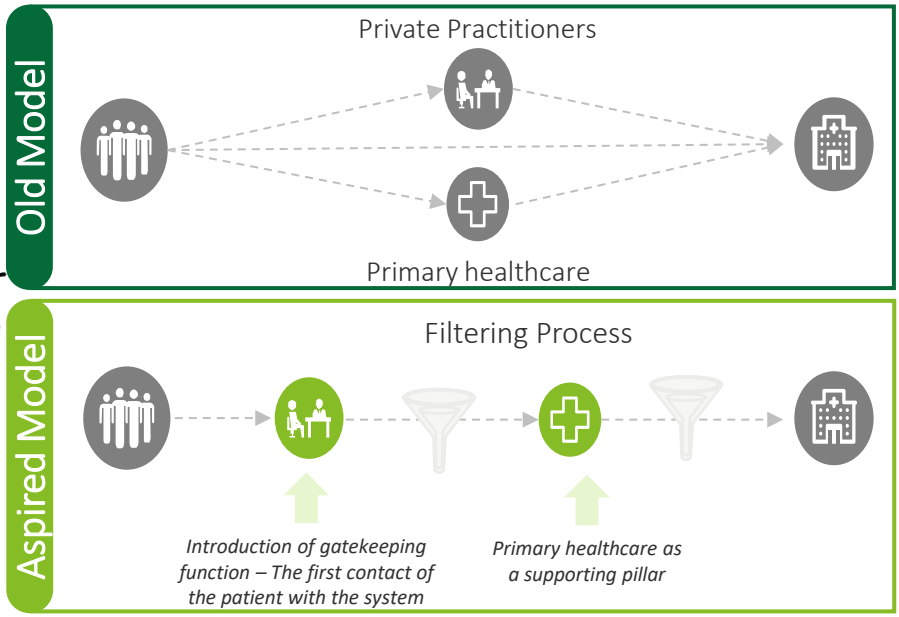
The reform introduces **structured referral mechanisms** with GPs as the system's first point of contact. Patients will be triaged and referred based on clinical guidelines, while **primary healthcare becomes a central pillar** of the system.

The model leverages tools such as **telemedicine, digital triage systems and clinical decision support** to improve capacity and ensure consistency across regions. It also creates incentives to **expand GP availability and participation**, ultimately enhancing care quality, system sustainability and long-term pharmaceutical stewardship.

Strengthening Primary Care

Implementing GP-centered gatekeeping can enhance system performance, ensure more rational prescribing, and improve care continuity

Proposal conceptualization



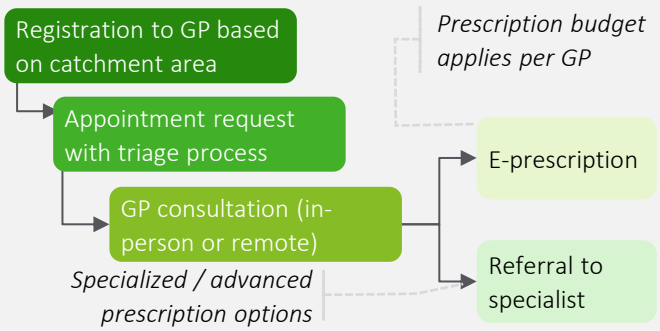
Key challenges:

- Inadequate HCP enrollment to cover the entire population
- Patients are used to freely moving around the system – cultural considerations
- Lacking infrastructure & digitalization in primary healthcare
- Access to primary healthcare inequalities (mainly due geography/ morphology)

Moving forward
Provide further incentives to HCPs to increase family doctor enrollment and geographic coverage
Develop structured patient pathways (pilot for specific diagnoses & specialties)
Integrate clinical decision support tools within EHRs to drive GPs clinical decision making and referral requirements
Leverage telemedicine to reach remote areas (e.g., empower selected PHUs to serve remotely specific islands)

Case Study Highlights

Structured referral patterns



Family doctors as gatekeepers

Accessing non-emergency care through the public health system requires referral from primary care; Portugal is expanding "Family Health Units", multidisciplinary teams based around groups of family doctors and with incentives to focus on local health priorities and personalized care provision.

Strengthening Primary Care

Reinforcing the role of primary care as the system's entry point can enhance continuity, reduce unnecessary specialist use and enable targeted demand management

Key Implementation Considerations

Cultural Transition

Launch targeted communication campaigns to shift patient habits away from direct specialist access and promote structured referrals through primary care. This will improve care continuity and appropriateness of treatment.

System & Operational Integration

Develop coordinated referral pathways with aligned IT systems across PHC units, GPs and hospitals to ensure seamless patient navigation and consistent implementation.

Performance Monitoring

Define key indicators (e.g., referral rates, wait times) and real-time feedback loops to measure gatekeeping impact and allow adaptive management of the referral system.

Clinical & Operational Support

Provide GPs with clinical protocols, training and digital tools to help manage triage decisions, referrals and prescribing responsibilities confidently and consistently.

Anticipated Impact

Improved Health Outcomes

Structured referrals ensure that patients receive clinically appropriate care early, improving disease control, reducing complications and strengthening long-term outcomes.

Equity in Access

Better allocation of GPs and referral oversight help bridge regional access gaps, especially in underserved areas, bringing essential care closer to those who need it most.

Efficiency of System Resources

Gatekeeping reduces unnecessary specialist visits and optimizes the use of healthcare capacity by directing patients to the right care level.

Indirect System Rationalization

Primary care coordination enables more stable and rational prescribing patterns, supporting better forecasting, budgeting and the sustainability of pharmaceutical spending.

Initial implementation timeline

12 months (design) / 12-36 months (implementation)

Ramping up Prevention Focus

Prevention is the long-term debt of the health system, and a necessary investment to rationalize resource allocation

Current State

Greece's approach to prevention **has evolved notably since the pandemic**, with growing focus across all three stages (primary, secondary and tertiary). While this marks a **positive shift**, **efforts remain uneven and must accelerate to align with leading international practices**.

Primary prevention efforts, particularly those targeting modifiable behavioral risk factors such as smoking, alcohol use, and other substance abuse, have much left to accomplish, as **cultural factors** continue to weigh on public health in these regards.

In terms of vaccination and early screening programs, current initiatives are towards the right direction with significant positive effects to public health. However, there are **significant limitations in measuring the cost-effectiveness of each campaign and comparing** to other interventions, while the **pharmaceutical costs** that result from these programs are **disregarded from cost measurements and the pharmaceutical budget.**

Tertiary prevention also remains limited in terms of **structured palliative and rehabilitative care** infrastructure, leading to fragmented support for patients with chronic or terminal conditions. Similarly, **chronic disease management lacks dedicated robust infrastructure** such as daily care centers, integrated care pathways, and multidisciplinary care teams.

Why it is important

Creating a more thoughtful prevention strategy that accurately measures cost and value to the system is paramount to provisioning **patient-centric public health policy**. The current implementation of these strategies make it **difficult to analyze where resources should be allocated** for maximum effectiveness in identifying and intervening before diseases require more drastic and expensive interventions (treatments, surgery, loss of work productivity).

Proposal's Rationale

The proposal introduces a **coordinated, system-wide approach** to prevention by strengthening actions across all levels. It aims to **define specific objectives for each level, embed measurable KPIs and promote the use of real-time data** to guide design and delivery. Targeted screening and timely vaccination are key tools to shift from reactive to proactive care.

At the same time, the proposal **emphasizes the importance of building the necessary infrastructure to support long-term impact and better aligning services with population needs**. By improving access, targeting high-risk groups and ensuring continuity of care, the system becomes more resilient, equitable and cost-effective in the long term.

Ramping up Prevention Focus

While key steps have already been taken in all levels of prevention, more coordinated and targeted action is needed to maximize health and system-level outcomes

Proposal conceptualization

Primary

Awareness Campaigns

Maintain & enhance existing efforts around behavioral factors, including:
- Smoking cessations
- Healthy lifestyle / obesity
- Substance use

National Vaccination Program

Set clear vaccination targets based on NIP proposals (link to respective budget), review data on vaccination progress & make corrective actions to increase coverage for specific areas (e.g., seasonal flu, HPV)

Secondary

Early Diagnosis Screening Programs

Carry on with the implementation of the ongoing screening programs (breast, cervical & colorectal cancers and CVDs) while:
- Review and share preliminary data on performance and identify corrective actions
- Consider introducing new screenings such as lung cancer screening with low-dose CT

Rare Diseases Screening

Adopt a holistic approach in screening for rare diseases by:
- Introducing gene-based neonatal screenings for rare diseases, similarly to today's approach for thalassemia
- Increasing engagement with horizon scanning platforms for focused on rare diseases

Tertiary

Care Infrastructure

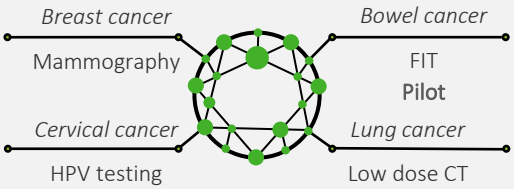
Invest in care infrastructure to support enhanced tertiary prevention results:
- Palliative care
- Rehabilitative care
- Chronic disease management (e.g., dialysis)

Chronic Disease Management

Enhance efforts in supporting chronic disease management through education campaigns & patient trainings (incl. focusing on adherence to medication)

Case Study Highlights

National Cancer Screening Program



Key characteristics:
- Evidence based & regular updates based on real-time data
- Design ensuring national reach & accessibility
- Public awareness & education to support screenings
- Informed choice of patient participation & confidentiality
- Coverage of follow-up tests

KPI framework

Participation rates	Coverage & reach
Timeliness of screening	Detection rates
Positive predictive value	Mortality reduction
Follow Up timeliness	Cost-effectiveness

Ramping up Prevention Focus

Targeted investments in prevention, supported by robust data and care integration, can enhance health outcomes, reduce burdens, and ensure equitable access early diagnoses

Key Implementation Considerations

Data Integration And Processing

Strengthen mechanisms for data collection and processing and ensure alignment with national health IT architecture and patient record systems for timely estimation of performance and costs.

Public Awareness

Strengthen and tailor communication campaigns to improve risk perception, promote participation in screening, and support adherence to healthy behaviors.

Care Pathway Integration

Ensure that preventive services are linked with follow-up care, including referrals to secondary and tertiary care, diagnostic follow-ups and chronic disease management facilities or providers.

Screening Equity Monitoring

Track screening uptake across regions and groups to identify access gaps and guide corrective action, ensuring equitable access to all modes of care and prevention initiatives.

Anticipated Impact

Better population health

Strengthened prevention improves long-term health outcomes, enhances quality of life, and reduces disease burden at the population level with significant savings and gains to the economy.

Major Disease Early Detection

Expanded and better-targeted screening programs enable earlier identification of conditions like cancer and CVDs, improving treatment outcomes and survival rates.

Future cost-avoidance

Prevention and early diagnosis reduce advanced treatment needs and disability, lowering both direct and indirect costs such as productivity loss and long-term care dependence.

Equitable Access to Diagnostics

Designing programs in a structured manner and improved outreach methodologies lead to higher uptake across population groups, addressing gaps in access and health outcomes.

Initial implementation timeline

12 months (design) / 12-24 months (implementation)

Wrap-up

Strategy Validation

The set of proposed interventions, incorporated in the roadmap, tackle all identified imperatives

The challenges facing the pharmaceutical system are multifaceted, stemming from structural inefficiencies embedded in the system over many years. These issues are deeply interconnected and often mutually reinforcing. It is therefore essential to recognize that the pharmaceutical system **cannot be fixed through singular, isolated policies** but with a **coordinated and holistic approach.**

The 10 proposals presented are intentionally designed as a **cohesive and holistic set of reforms** that reflect the **multidimensional nature of pharmaceutical policy**. Their design reflects the key imperatives of a health system, adapted to the specific challenges and constraints of the Greek context and **balancing feasibility with long-term system transformation**. Taken together, they offer a roadmap toward a system that is more **efficient, equitable, and focused on value**.

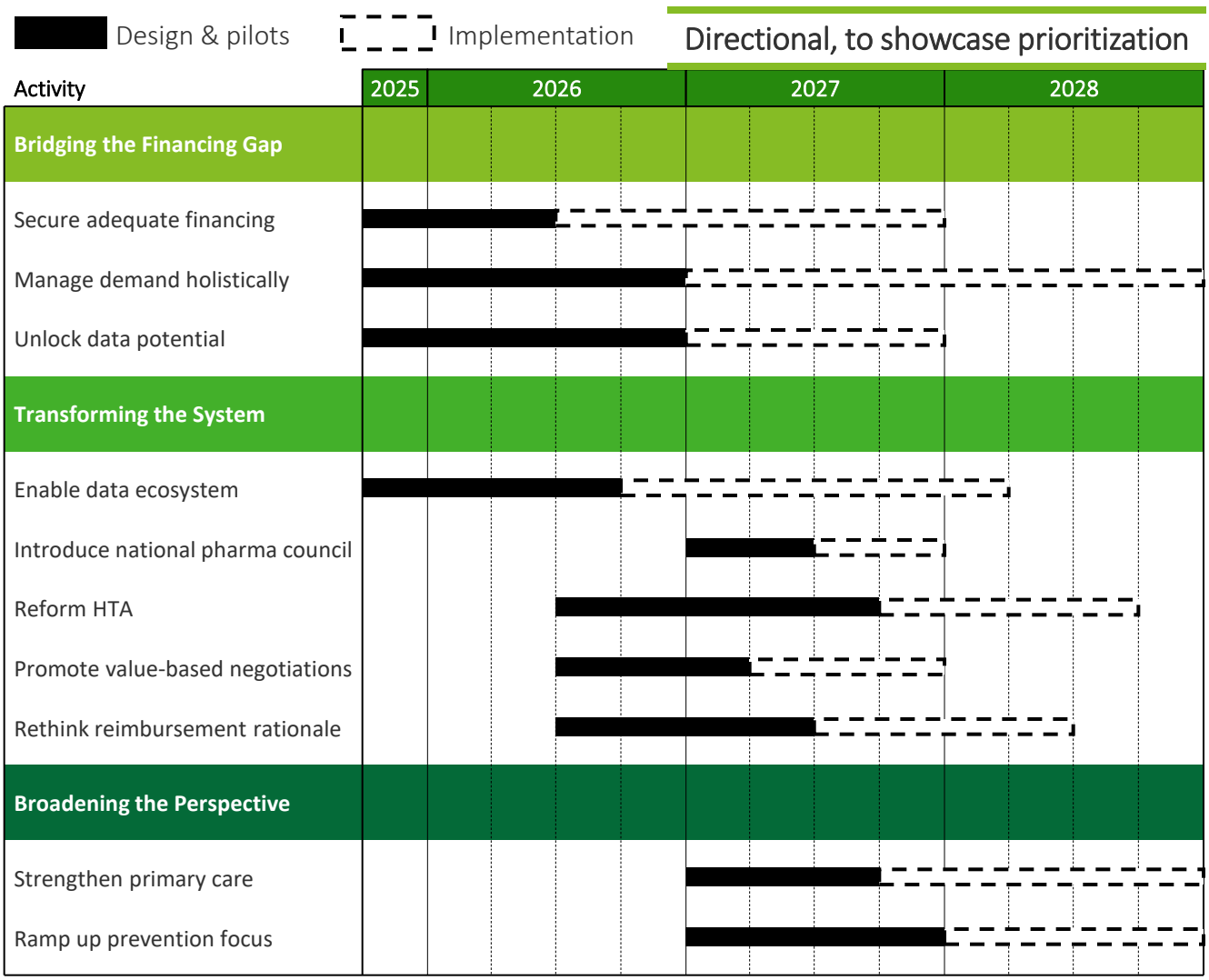
	Patient-centric	Forward-looking	Fair	Flexible	Transparent	Attractive	Holistic	Focused on value	Data-driven	Collaborative
Secure Adequate Financing	✓	✓	✓	✓		✓	✓			
Manage Demand Holistically	✓	✓	✓		✓	✓			✓	
Unlock data potential	✓	✓		✓	✓	✓			✓	
Enable data ecosystem		✓			✓	✓		✓	✓	✓
Introduce pharma council		✓			✓		✓			✓
Reform HTA		✓				✓		✓	✓	
Promote value-based negotiations	✓				✓		✓	✓	✓	
Rethink reimbursement framework	✓		✓				✓	✓		
Strengthen Primary Care	✓						✓	✓		
Ramp up Prevention Focus	✓	✓					✓	✓	✓	

Indicative Implementation Timeframe

The proposed reforms can be implemented in phases but the bulk of them can be in place yielding results by 2028

The plan requires a **phased, multi-year implementation approach for key reforms**, structured across three strategic pillars. It **prioritizes early action on financial sustainability, while allowing adequate time for more complex** system-wide transformations, such as establishing a national data ecosystem.

It is important to note that **this timeline is indicative** and **assumes strong political commitment and alignment among key stakeholders**. Several initiatives **may proceed at a different pace depending on institutional readiness, regulatory progress** and **implementation capacity**. Additionally, dependencies between reforms, such as data unlocking as a prerequisite for monitoring and value-based agreements, may require **adaptive sequencing**. Overall, this roadmap should be seen as directional, designed to support prioritization and alignment rather than as a rigid schedule.



Promoting Reciprocity

The industry can support implementation across most initiatives, while an enhanced investment clawback can drive economic activity through reciprocity.

Indicative synergetic areas with industry

Roadmap items	Potential industry support
Secure Adequate Financing	Innovation fund design & mechanics, implementation support
Manage Demand Holistically	HCPs awareness increase, protocol design and regulatory support
Unlock Data Potential	Support digitalization efforts with know-how and good practices
Enable Data Ecosystem	Provision of good practices from global networks, co-invest in data infrastructure, support ecosystem's design
Introduce National Pharma Council	Provision of good practices from global networks, implementation support
Reform HTA	Provision of good practices from global networks, implementation support
Promote Value-based Negotiations	Provision of good practices from global networks, implementation support
Rethink Reimbursement framework	Provision of good practices from global networks, specialized know-how provision
Strengthen Primary Care	Provision of good practices from global networks, patient pathways design support
Ramp Up Prevention Focus	Provision of good practices from global networks, patient pathways design support, screening programs design

Reciprocity mechanism

Proposal to extend investment clawback incentives, covering a wider scope of investment activities; Indicatively:

Manufacturing & Production R&D — *Equipment and plant modernization, R&D infrastructure, new production capability etc.*

Clinical Trials — *All stages clinical trials with extended application timelines vs the previous investment clawback application*

Digital / Data infrastructure — *Data hubs, RWD collection / infrastructure, health data applications/registries, disease-specific CoEs, clinical trials hub*

Scientific Forums — *Scientific events aiming at promoting knowledge alongside educating for utilizing innovative tools and therapies*

Appendices

Appendix I - Pharma Policy Overview

Pharma policy overview

Over the past five years, the government has announced a series of measures that vary in terms of implementation maturity

#	Policy title	Year announced	Description	Implementation stage	Anticipated impact
1	Separate funding for cancer biomarkers	2025	Separate budget to reimburse cancer biomarkers	Under implementation	>€250m savings
2	Split retail budget for generics/off-patent	2025	Separate retail budget and industry returns policy for generics/off-patent	Under implementation	
3	Expand electronic pre-approval system	2025	Extension of the Electronic Pre-approval system to more medicine categories	Under implementation	
4	Pharmacist pre-dispensing	2025	HMVO to enable pharmacists to dispense medicines to certain patients before they get their prescription	Under implementation	
5	Implement IFET purchasing strategy	2024	Digital connection with EOF for emergency orders, use of AI to optimize supplier selection	Partially implemented	
6	Establish organization to combat counterfeit medicines	2024	Establishment, launch and full connection of the Hellenic Medicines Verification Organisation (HMVO)	Implemented	
7	Generic reimbursement pricing changes	2024	Abolition of retail equation with reimbursement price for generic medicines, additional charge <€3	Implemented	<€40m savings
8	Abolish 5/11 rule	2024	Removal of the 5/11 countries rule; optional HTA submission after distribution by IFET >6 months	Not implemented	
9	Medicine consumption monitoring	2024	Electronic Pre-authorisation System monitoring using EOPYY's Business Intelligence (BI) system	Not implemented	
10	Establish HDPA	2024	Establishment of the National Access Body according to the new European Health Data Space Regulation	Not implemented	
11	DRG system in hospitals	2024	Implement DRGs for hospital funding	Partially implemented	
12	Lock and monitor e-prescriptions	2024	Adding new filters/barriers and linking with patient registries for highest spending categories	Not implemented	€50m savings
13	Expand e-prescriptions to in-patient channel	2024	Ensure granular inpatient consumption data is collected and digitized in a timely manner	Not implemented	

Source: News Reports and Official Announcements

Pharma policy overview

Over the past five years, the government has announced a series of measures that vary in terms of implementation maturity

#	Policy title	Year announced	Description	Implementation stage	Anticipated impact
14	Establish a task force to investigate overprescription	2024	Task force focused on investigating over-prescription with an initial focus on 5 categories	Partially implemented	
15	Retail distribution of high-cost medicines	2024	Distribute some high-cost medicines through retail pharmacies with a flat distribution fee	Not implemented	
16	Increase hospital funding from budget surplus	2024	Allocate €33m to the hospital budget from certain sub-budgets that were not overshot	N/A	€33m
17	Abolish protective measures for cheap hospital medicines	2024	Remove industry return protections for cheap hospital medicines priced >€15 and reallocate for those <€15	Not implemented	€20m savings
18	Price increase for low-cost medicines	2024	Up to 35% price increase for medicines previously priced <€10	Implemented	
19	Additional rebates to high-cost medicines	2024	Up to 3% additional rebate added as an amendment to legislation being considered	N/A	
20	MAH imports for medicines in shortage	2024	Set up a system for MAHs to import medicines in shortage instead of IFET	Not implemented	
21	Assessing electronic pre-approval requests	2024	Established a committee to assess pre-approval requests	Implemented	
22	Allocate clawback generated by IFET	2024	Allocate additional clawback from IFET imports to the MAHs whose drugs are imported	N/A	
23	Align HTA with EU regulation	2024	Implement the necessary legal framework to align national HTA with the EU framework	Not implemented	
24	Sharing consumption data with industry	2024	Create a consumption data platform for industry access	Partially implemented	
25	Treat SSN debtors as uninsured	2024	Those with unpaid insurance contributions will be considered uninsured	Not implemented	
26	Increase of public funding by €300m through RRF	2024	Allocates €80m to retail, €120m to hospitals, €100 to high-cost medicines	Implemented	

Source: News Reports and Official Announcements

Pharma policy overview

Over the past five years, the government has announced a series of measures that vary in terms of implementation maturity

#	Policy title	Year announced	Description	Implementation stage	Anticipated impact
27	Increase vitamins co-payment	2024	50% increase in vitamin co-payment rate	Implemented	>€30m
28	Remove inactive SSNs	2024	Inactive SSNs will be disabled and can no longer be reimbursed	Not implemented	€100m
29	Prescription by brand name	2024	Allow an additional 15% of prescriptions by brand name for generic medicines only	Implemented	
30	Orphan disease registry and catalog	2024	Implement a database about disease prevalence and patient information for rare diseases	Not implemented	
31	Differentiated clawback treatment for orphan medicines	2024	Apply different industry returns policies for orphan medicines	Partially implemented	
32	Voluntary transfer to the negative list	2024	Allow low-cost medicines to leave the positive list	Implemented	€100m savings
33	Joint procurement for certain critical medicines	2023	Establishment of interconnected national and EU Joint Procurement processes (HERA)	Partially implemented	
34	Prescription limits to doctors	2023	Limits prescriptions based on expected duration of treatment or with a per patient limit	Not implemented	
35	DTC delivery for high-cost medicines	2023	Organize high-cost medicine delivery directly to patients' homes	Partially implemented	
36	Implement a system to monitor drug shortages	2023	Measures including ΗΣΠαΔΙΦ (σύστημα παρακολούθησης διακίνησης φαρμάκων)	Implemented	
37	Allocation of €200m of additional funding to pharma budget	2023	Allocates €75m to retail, €65m to high-cost, €60m to hospital	Implemented	
38	Broadened age brackets for breast cancer screening	2023	Announced inclusion of more age groups into the "Fofi gennimata" program	Implemented	
39	Measures to combat parallel exports	2023	Measures targetting companies exporting drugs during shortage periods	Implemented	

Source: News Reports and Official Announcements

Pharma policy overview

Over the past five years, the government has announced a series of measures that vary in terms of implementation maturity

#	Policy title	Year announced	Description	Implementation stage	Anticipated impact
40	Pause co-payments in disaster-stricken areas	2023	Suspension of co-payments for Thessaly residents (2023 floods)	Implemented	
41	Expanding national EHR	2023	Expanded app to include hospitalizations and some test results	Partially implemented	
42	Strategic reorganisation of EOPYY and upgrading of EOF	2022	Strategic reorganization and digital transformation of EOPYY	Not implemented	
43	Flu shot provided free of charge without prescription	2022	Some population groups can receive the flu shot free of charge and without a prescription	Implemented	
44	Temporary ban on parallel exports	2022	The parallel export and intra-EU movement of 75 pharmaceutical products was temporarily banned	Implemented	
45	E-prescription streamlined	2022	Reducing required paperwork for patients with chronic illnesses	Implemented	
46	Strategic plan for public health	2022	Includes prevention policies of €300m (screening for various diseases)	Partially implemented	
47	Incentives/counter-incentives for signing up to family doctors	2022	Priority appointments for people who sign-up, increased co-payment for those who don't sign up	N/A	
48	Announced breast cancer screening program	2022	"Fofi Genimata" program presented, up to 1.3m women eligible for testing	Implemented	
49	Cancer care management program - digitalization initiatives	2022	Includes cancer registry, online platforms for care coordination and patient information applications	Partially implemented	
50	Implement closed sub-budgets	2021	Law allowing the setting of closed sub-budgets for certain drugs or categories first announced	Implemented	
51	Abolishing co-payment for low-income pensioners	2020	Pensioners earnings less than ~€650/month will be exempt from co-payments	Implemented	

Source: News Reports and Official Announcements

Pharma policy overview

Over the past five years, the government has announced a series of measures that vary in terms of implementation maturity

#	Policy title	Year announced	Description	Implementation stage	Anticipated impact
52	Restrictions to prescribing for uninsured population	2020	Restrict prescriptions to uninsured only from public/primary care doctors	Implemented	
53	Temporary exemption from co-payment for uninsured	2020	Exemption from co-payment for uninsured during the Partially implemented of the pandemic (6/20)	Implemented	
54	Measure to ensure all medicines are dispensed only with a prescription	2020	MoH committed to enforcing prescription restrictions for all medicines	Not implemented	

Source: News Reports and Official Announcements

Appendix II – EU Good Practices

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
1		Uninsured population treatment	France provides health benefits to uninsured populations through dedicated programs, funded separately from the general health insurance system	Secure adequate financing
2		Uninsured population treatment	The Portuguese parliament has approved limited access to the healthcare system for non-country residents (2024)	Secure adequate financing
3		Uninsured population treatment	Public spending reimburses 60% of the cost for undocumented population	Secure adequate financing
4		Screening programs - economic evaluation	NICE guidelines for screening programs assume direct and indirect costs based on assumptions of population that will require follow-ups	Secure adequate financing
5		Innovation fund/ access tools	Fully innovative medicines in the innovation fund receive favorable treatment	Secure adequate financing
6		Innovation grants	Innovation Fund Denmark funds innovation and supports decentralized clinical trial initiatives	Secure adequate financing
7		Prescription protocols drafting	French National Authority for Health is responsible for drafting protocols in collaboration with medical societies and committees; provides the general framework and ensures adherence to national policies	Manage demand holistically
8		Simplification of protocols system	Prescription guidelines follow a traffic light principle, with varying degrees of freedom and complemented by monitoring for "dark-yellow" group	Manage demand holistically
9		Protocol support and awareness	The Innovation Office reports on innovative therapies to health authorities etc., providing support for use under specific or exceptional conditions	Manage demand holistically
10		Auditing prescription behavior	Monitoring of doctors' prescription budgets can lead to payback if 25% thresholds are exceeded	Manage demand holistically
11		Active demand management	NHS Trusts face monthly capital/resource limits and monitor expenditure; deviations above set thresholds require justification	Manage demand holistically

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
12		Link of protocols to reimbursement	Italy monitors appropriate medicine use through AIFA's registries and OsMed's analysis of prescription and consumption data	Manage demand holistically
13		Cost effective mix promotion	Portugal conducts annual price reviews under stringent rules; price increase limits are based on initial retail price	Manage demand holistically
14		Cost effective mix promotion	Spain provides targeted financial incentives to HCPs and streamlined access process for biosimilars	Manage demand holistically
15		HCP prescription behavior	In the UK, NHS and biosimilar associations run dedicated educational campaigns and platforms for HCPs and patients to improve awareness, safety understanding, and adoption of biosimilars	Manage demand holistically
16		HCP prescription behavior	In France, pharmacists receive enhanced financial incentives (through higher margins and discounts) to substitute branded medicines with generics	Manage demand holistically
17		EKAPY's role in demand management	Amgros negotiates prices and MEAs for all new medicines and indications, while actively monitoring stock levels and sharing procurement data	Manage demand holistically
18		Guidelines review framework	Portugal's Infarmed updates guidelines and reassesses reimbursement conditions when significant economic or evidence-based changes arise	Manage demand holistically
19		Biosimilar benefit sharing	In France, pharmacies receive 20% of the biosimilar–reference price difference, while hospitals get 20%, increasing to 30% under the Article 51 pilot	Manage demand holistically
20		Budget structure	All EU countries examined structure their budget around two channels – hospital & retail – based on purchasing modes or intended consumption pattern	Manage demand holistically
21		Budget structure and industry returns mechanics	Italy allocates its pharmaceutical budget to two main channels—retail and hospital—and operates a dedicated innovation fund	Manage demand holistically
22		Management of excess spending	Industry signs a recurring agreement with the state that stipulates budget limit and adjusts limit with GDP growth	Manage demand holistically

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
23		Copayment & taxation	In the UK, prescription medicines dispensed via retail pharmacies are zero-rated for VAT	Manage demand holistically
24		Investment clawback	Pharmaceutical framework agreement stipulates R&D expenses that can be used to offset clawbacks	Manage demand holistically
25		Digitally mature system	Regional EHRs are centralized into national registries; implements data specifications/standards with error alerts to HCPs and data quality reports	Unlock data potential
26		Data quality management	Denmark utilizes AI models to extrapolate missing data from cancer registries and facilitate real-time updates to registries and databases	Unlock data potential
27		Data quality management	UK publishes data quality maturity index to assess and benchmark providers while also including information and guidelines for HCPs (e.g., common mistakes)	Unlock data potential
28		System monitoring and triggers	When health spending nears fixed budget limits, the UK system enforces fiscal controls — including price negotiations and industry rebates — to contain costs	Unlock data potential
29		Budget process and key inputs	Belgium uses short-term (including estimated future cost savings) and long-term projections based on 2.5% of the population and average DDD, with 3-year forecasts from industry	Unlock data potential
30		Access to financial information	Italy publishes a comprehensive OsMed report—detailing pharmaceutical spending and industry returns for the previous year—by Q3	Unlock data potential
31		Access to financial information	Portugal maintains publicly available dashboards with consumption data by therapeutic group and region, through Infarmed's platform	Unlock data potential
32		Horizon scanning	Belgium uses horizon scanning during the clinical trial phase, with outputs feeding into short-term pharmaceutical budget projections	Unlock data potential
33		Beneluxa initiative	BeNeLuXa is an international Horizon scanning initiative that identifies and prioritizes emerging technologies	Unlock data potential

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
34		Data analysis capabilities	Belgium operates a multi-stakeholder Knowledge Centre that leverages advanced data and multidisciplinary expertise to advise policy and reporting decisions	Unlock data potential
35		Data analysis capabilities	Portugal has institutionalized performance benchmarking and monitoring, supported by BI tools, for HCPs and administrators	Unlock data potential
36		Health data permit authorities	Findata provides access to a broad array of social and health data—including pre-processed aggregated datasets—and offers advanced research tools under a fee-for-service revenue scheme	Enable data ecosystem
37		Health data permit authorities	The French HDPA provides a holistic access framework and incentives for researchers' efforts to solve health data challenges (research grants & release of specific data challenges with monetary prizes)	Enable data ecosystem
38		Health data permit authorities	As part of the EHDS2Pilot, Spain aims to define and build common IT infrastructure, standards, metadata catalogs and interoperability, legislate the respective framework and document acceptable uses	Enable data ecosystem
39		Biobank databases	Danish National Biobank collects and stores biological and blood samples from hospitals and clinics, including newborn dried blood spots (PKU cards) since birth	Enable data ecosystem
40		Fee-for-service HDPA	Findata operates a fee-for-service model for third-party access—including industry and academia—to secondary health and social data	Enable data ecosystem
41		Health data permit authority	Findata manages access to health data through a secure remote-desktop environment and is supervised by an inter-ministerial working group and the national data authority	Enable data ecosystem
42		Health data permit authority	Health Data Hub provides technical support for data collection and standards and publishes "Data Challenges" with monetary rewards for researchers to develop health data applications	Enable data ecosystem
43		Systems integrations & interoperability	Sweden operates a metadata tool catalog to help users discover and navigate existing decentralized health data registries	Enable data ecosystem
44		Systems integrations & interoperability	The Danish Health Data Authority and MedCom define and enforce data standards and technical specifications for the national health data infrastructure	Enable data ecosystem

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
45		National pharmaceutical strategy	Spain includes inter-ministerial coordination, joint monitoring of implementation, a collaborative forum for public/private alignment and public-private partnership R&D initiatives	Introduce national pharma council
46		National life sciences council	The Danish Life Science Council advises on pharma strategy for clinical trials, financing instruments, health partnerships for innovation programs, data utilization framework and manufacturing	Introduce national pharma council
47		Clawback notes	Portugal's framework agreement mandates quarterly clawback calculations and settlement within 2 quarters, overseen by an inter-ministerial commission with industry involvement	Introduce national pharma council
48		Medical research act	The framework includes incentives for clinical trials, such as pricing for German participation, a committee for complex designs, and a structure to standardize research	Introduce national pharma council
49		Clinical assesment ratings	SMR addresses disease severity and therapeutic strategy to determine reimbursement rate, while ASMR measures improvement compared to existing options, influences prescribing and price	Reform HTA
50		"Pharmascan" data platform	The UK government is establishing a central data service to enable streamlined access to regulatory, trial, and budget data, supporting pathway planning, HTA scheduling and fast-track trial identification	Reform HTA
51		Health technology assessment	UK focuses on clinical and cost-effectiveness within defined ICER thresholds, incorporates stakeholder reviews and extensive RWE, and operates dedicated pathways for highly specialised and orphan medicines	Reform HTA
52		Innovation fund / access tools	Orphan drugs MAHs submit an abbreviated file to the HTA committee and benefit form a shorter assessment process	Reform HTA
53		IFET rationalization	Within Portugal's compassionate use framework, the MAH provides the medicine free of charge for patients with life-threatening diseases	Reform HTA
54		HTA process	Ireland evaluates budget implications meticulously through HTA-guided assessments that integrate clinical effectiveness and cost-effectiveness criteria	Reform HTA
55		"New Examination and Treatment Methods" process	Germany's NUB mechanism allows MAHs of orphan or critical ATMPs to obtain temporary reimbursement through hospitals—bypassing the standard 3-year DRG entry process	Reform HTA

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
56		Holistic negotiation premise	Sweden conducts holistic economic assessments—covering non-pharma costs and socio-economic impacts like productivity loss—and applies long-term modelling when clinical data is limited	Promote value-based negotiations
57		Framework enabling risk-sharing tools	Belgium enables increased penetration of MEAs by establishing robust RWD collection (registries, Rx), centralizing data for secondary use (Knowledge center) and a clear legal framework for clinical trials	Promote value-based negotiations
58		Holistic perspective in procurement	Horizon Scanning unit in Denmark leads pipeline meetings with industry and monitors data to inform budgeting forecasts, tender planning, HTA prioritization, and fast-track identification	Promote value-based negotiations
59		MEAs and other risk-sharing tools	In Belgium, MEAs accounted for >20% of public spending, most commonly using % or fixed rebates or budget capping	Promote value-based negotiations
60		Negotiations premise	Medicine pricing negotiations are grounded in clinical and cost-effectiveness; negotiations include both voluntary and statutory schemes featuring spending caps and industry rebates for overspend	Promote value-based negotiations
61		Value-based pricing	France sets medicine prices primarily on clinical benefit (ASMR), with external reference pricing used as a secondary criterion	Promote value-based negotiations
62		System reciprocity	France uses managed entry agreements (rebates and expenditure caps) to support a fair exchange between the government and industry, balancing cost containment with innovation support	Promote value-based negotiations
63		Managed entry agreements	Italy uses MEAs (mainly volume-based financial agreements) to override rigid innovation entry processes	Promote value-based negotiations
64		Central procurement	The NHS operates national framework agreements covering the full scope of medicines procurement under the Medicines Procurement & Supply Chain framework	Promote value-based negotiations
65		Pricing	Spain negotiates prices based on EU reference pricing, budget impact, and cost-effectiveness; generics are set at 60% and biosimilars at 70% of the originator's price	Promote value-based negotiations
66		Pricing	Portugal applies external reference pricing using the average wholesale price from France, Italy, Slovenia, and Spain; generics capped at 50%, and biosimilars at 70–80% of the originator price	Promote value-based negotiations

Pharma policies

A series of EU-based good practices were identified and examined to support recommendations and analyses, either through validating or dismissing key directions

#	Country	Title	Description	Classification
67		Tendering rebates	German sickness funds conduct tender-based rebate contracts at API level, enabling exclusive supplier status through negotiated price or volume incentives	Promote value-based negotiations
68		Reassesment frameworks	All medicines in France are reassessed every five years—or sooner if new significant data emerges—with published decisions defining therapeutic benefit and reimbursement rate per active substance	Rethink reimbursement framework
69		Reassesment frameworks	Public authorities can request a reimbursement renegotiation based on new data such as significant budget impact, excessive precribing or insufficient cost-effectiveness	Rethink reimbursement framework
70		Co-payment schemes	In Belgium, reimbursement scales by disease severity: vital medicines receive 100% coverage, important treatments 75–85%, and comfort medicines about 50%	Rethink reimbursement framework
71		Co-payment schemes	Spain applies an income-based copayment scale—40%, 50%, or 60%—with high-income earners paying the maximum 60%	Rethink reimbursement framework
72		Co-payment schemes	In France, the copayment rate is determined by SMR — the assessed clinical benefit — with higher benefit leading to lower patient contributions	Rethink reimbursement framework
73		Early access programs	MAHs may request early access, doctors compassionate use; price is free or based on other uses, with reimbursement if final price is lower	Rethink reimbursement framework
74		Structured referral patterns	Patients register with a GP in their catchment area, undergo triage via NHS Pathways and receive GP consultation (in-person or remote) followed by an e-prescription or specialist referral	Strengthen primary care
75		Family doctors as gatekeepers	Non-emergency care in Portugal requires referral from primary care; services are delivered through multidisciplinary family health units with financial incentives tied to local health goals	Strengthen primary care
76		National cancer screening program	UK targets four priority cancers, using real-time KPIs and monitoring to drive performance while supporting public awareness and education	Ramping up prevention focus
77		Proactiveness	National Prevention Plan guides regional health authorities in implementing and monitoring prevention with KPIs and workplace promotion	Ramping up prevention focus

Appendix III - Budget Impact Assumptions

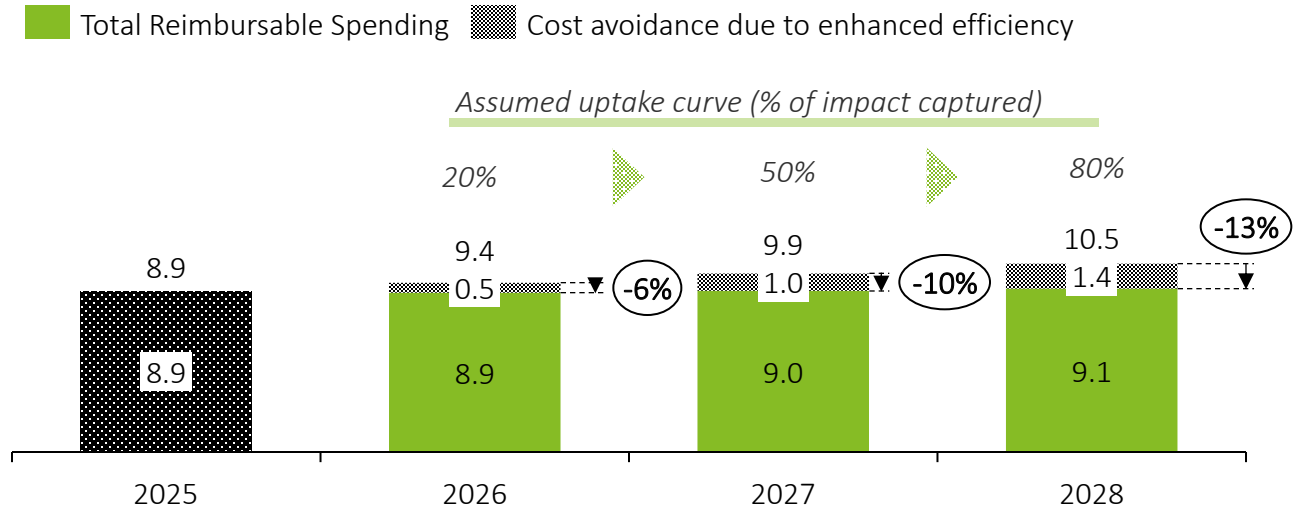
Manage Demand Holistically

The holistic adoption of prescription protocols and monitoring mechanisms are expected to yield a total pharmaceutical spending reduction of ~13%

Table 9. Budget Impact Assumptions – Manage Demand Holistically, Sources

	Source	Focus area	Anticipated Impact	Relevant channel	Adj. Factor
Protocols	American College of Physicians	Therapeutic substitution	10%-20%	Retail & High Cost	50%
	Pharmacy Benefit Mgmt. Institute	Formulary & utilization management strategies	13%-28%	Retail & High Cost	
E-prescription in hospitals	Institute for Clinical & Economic Review	Hospital pathways & prescription protocols	10%-20%	Hospital	N/A
	French Health Ministry	Management protocols & prior authorization	10%-20%	Hospital	
Audit, benchmarking & quotas	KBV	Benchmarking & quotas	1.5%-2.0%	Total	N/A
	NHS Digital	Prescription audits & benchmarking	1.0%-3.0%	Total	
	Dutch Healthcare Authority	Audit & feedback system	1.0%-2.0%	Total	
High-cost treatments validation	European Society of Medical Oncology	Prescription validation through CoEs	10%-20%	High Cost	50%
	NICE	Prescription validation through CoEs	15%-20%	High Cost	

Figure 17. Preliminary Budget Impact, in €b

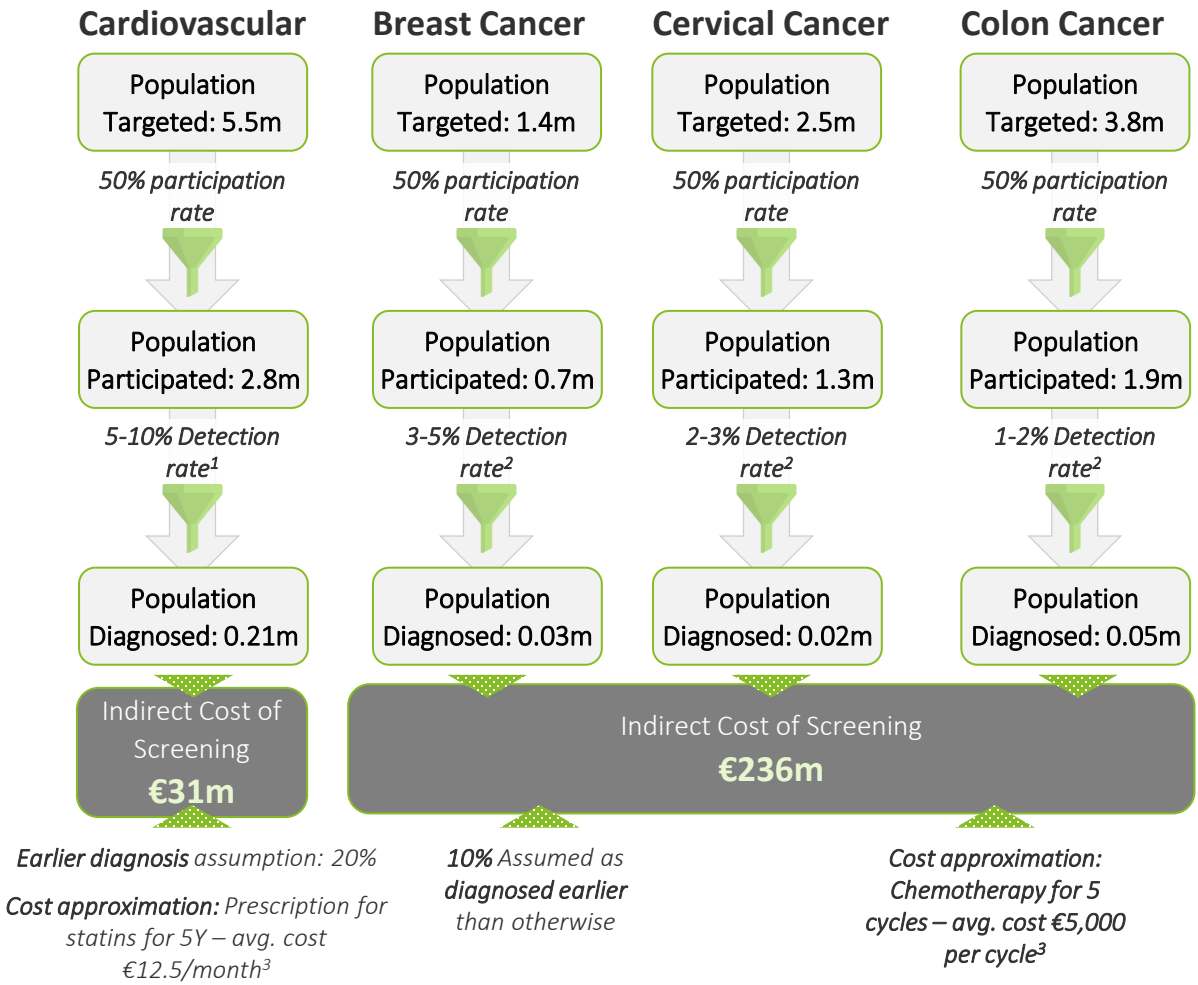


Source: Institute for Clinical & Economic Review, American College of Physicians, Pharmacy Benefit Mgmt. Institute, French Health Ministry, Deloitte analysis

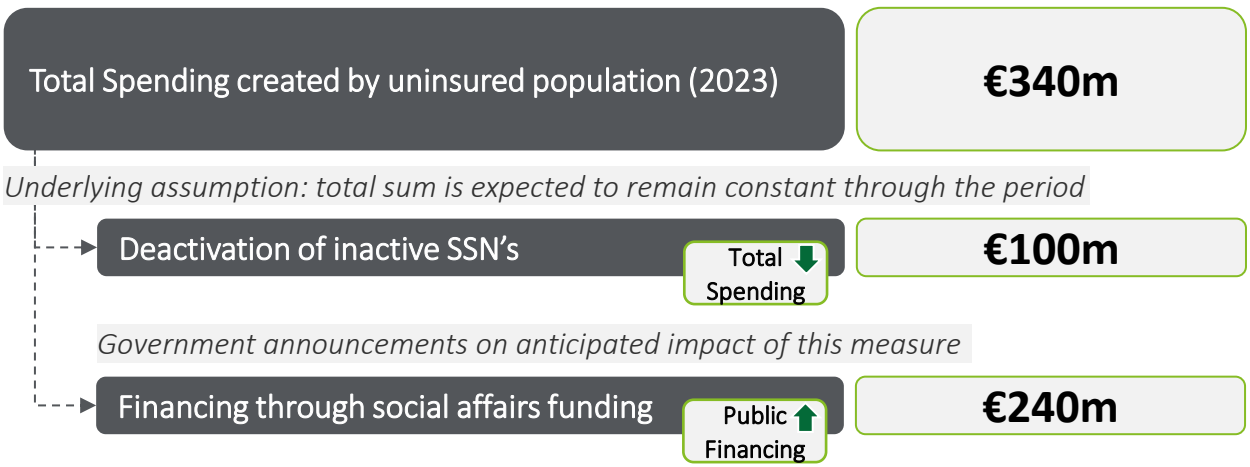
Secure Adequate Financing

The indirect cost of screening for existing programs is estimated at ~€267m, while the uninsured population accounts for a total of €340m in spending

Indirect Screening Cost Approximation



Pharmaceutical Costs for the Uninsured



Source: [1]American Heart Association, [2]American Cancer Society, [3]EOPYY

Secure Adequate Financing

The overflow of protection measures is estimated at ~€113m, while containing IFET is expected to yield €140m in spending reduction, along with €156m in innovation funding

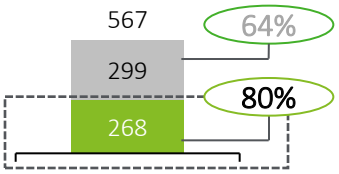
Protective Measures

Hospital Channel

Public spending, in €m (2023)

Available Budget

Closed Sub-Budgets



Key assumptions for value penetration:

- €0-5: 8%
- €5-15: 4%
- €15-30: 2%

Clawback ceilings:

- €0-5: 0%
- €5-15: 20%
- €15-30: 30%

Pricing Tier	Nominal Spending	Hyp. Returns	Derived Returns	Δ
€0-5	€78m	€62m	€0m	€62m
€5-15	€35m	€28m	€7m	€21m
€15-30	€16m	€13m	€5m	€8m
				€91m

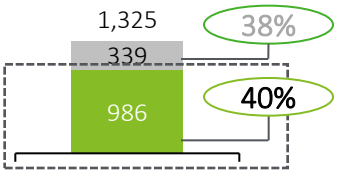
Source: SfEE, Desktop research, Deloitte analysis

Retail Channel

Public spending, in €m (2023)

Available Budget

Closed Sub-Budgets



Key assumptions for value penetration:

- DTC<€0.2 8%

Clawback ceilings:

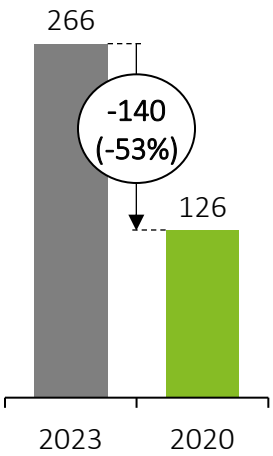
- DTC<€0.2 10%

Pricing Tier	Nominal Spending	Hyp. Returns	Derived Returns	Δ
DTC< €0.2	€74m	€29m	€7m	€22m
				€22m

Source: SfEE, Desktop research, Deloitte analysis

IFET Spending

Figure 18. IFET Sales, in €m



Target: Contain IFET at 2020 levels through enhanced monitoring, surveillance and scrutiny

Given that the period 2014-2019 there were not many innovative medicines entering the market, 2020 is considered a representative year for IFET's operations

Source: SfEE, Desktop research

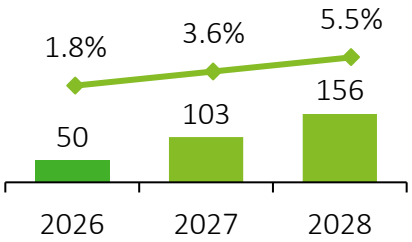
Innovation fund assumptions

Figure 19. Innovation Fund Assumptions, in €m

IF Financing, in €m

as a % of public budget

Target: Progressively increase IF financing, reaching benchmarks



Source: SfEE, Desktop research

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