Implementing the Recovery and Resilience Fund initiative to reduce pharmaceutical expenditure clawback in Greece: The impact on pharmaceutical spending and on national economy

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Mylonas C.[1], Dalakaki E.[1], Skroumpelos A.[1], Karokis A.[1]

[1] MSD Greece, External Affairs department, Athens, Greece

INTRODUCTION

- In 2012 the Clawback (CB) mechanism was introduced in pharmaceutical policy in Greece, establishing a fixed cap on public sector financial contribution, albeit with no limits on total purchases. The difference between total purchases and public sector contribution cap is fully returned by the pharmaceutical companies in the form of clawback charges.
- This cost – shifting strategy, accompanied by increasing patient copayments, led to industry CB levels increase from €75M in 2012 to €1,461M in 2021 (Fig. 1).
- Under the Recovery and Resilience Fund (RRF) 'Greece 2.0 initiative, the government has agreed to reduce overall pharma CB levels by €900M between 2022-2025 otherwise government funds of equal amount should be injected to the public pharmaceutical budget.

OBJECTIVE

- The study aims to identify potential structural reforms and their impact on pharmaceutical spending to achieve RRF targets as well as the impact of RRF success on the different stakeholders (Government, Patients, Companies)

METHODOLOGY

- An economic model was developed to predict annual pharmaceutical expenditure until 2025.
- A list of structural pharmaceutical policy interventions were identified in the literature and various stakeholders' policy proposals (e.g. PIF Roadmap). Their impact on pharmaceutical spending was quantified. The interventions were distinguished in short term measures (pricing, volume, reimbursement etc.) and medium-long term measures (Protocols, Horizon Scanning, Registries etc.).
- Pharmaceutical pricing data were retrieved by official price bulletins (PB). Pharmaceutical consumption was retrieved by private and public databases (IQVIA reports, IQVIA Panel Data, PnA Database, EOPYY) in order to quantify the impact of short-term measures on expenditure and clawback (Table 1). Literature review and own calculations were employed to quantify the relative impact of long-term measures on expenditure and consequently on CB.
- Additional funding measures for the system were not considered in the analysis. Measures to increase spending have already been legislated such as increasing the pharmaceutical budget based on GDP growth.

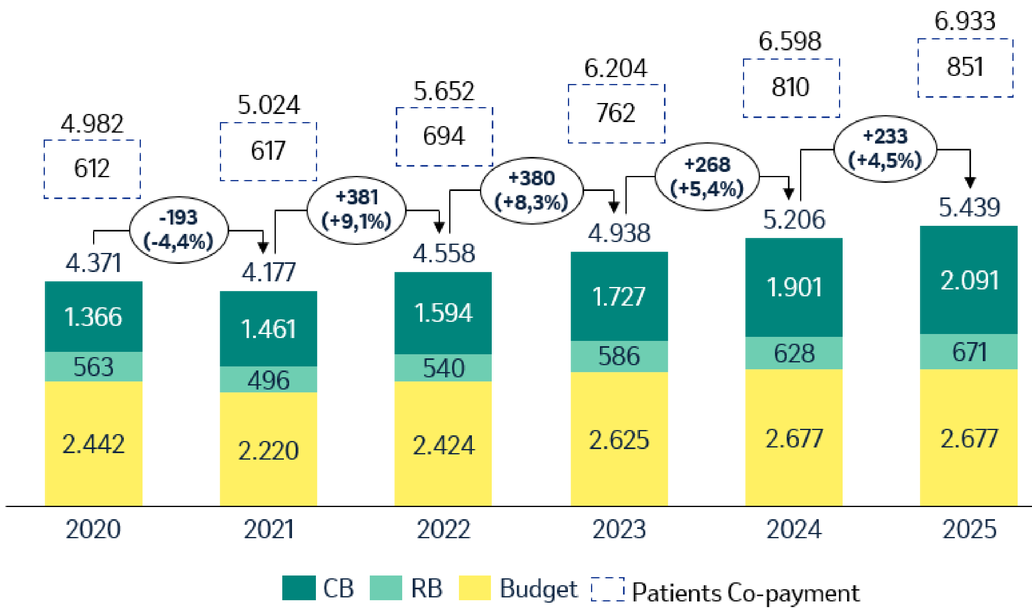
RESULTS

- The analysis provides a comprehensive set of interventions that address pharmaceutical policies regarding a) pricing, b) reimbursement and c) volume control. Implementing these policies might potentially provide savings of €1.620M over a period of 5 years. In a 5-year period, the implementation of those structural reforms will contribute to a) RRF target achievement b) up to €800M potential reduction of patients' copayments, c)up to €3.7 billion potentially reduced industry paybacks and d) up to €900 million potential benefit to government fiscal balance.

CONCLUSION

- Focusing on structural reforms, providing appropriate economic incentives, employing data-driven efficiency-enhancing policy interventions and dynamic monitoring can benefit patients, government, and industry, by reducing patient co-payments, improving fiscal balance, and releasing resources to the real economy.
- Due to the volatility of pharma environment, clawback and rebates are constantly changing variables and thus the results of the present study represent a snapshot of the present forecast of the future developments in pharma spending. . However, the relative impact of each of the measure remains relevant for future reform plans.

Figure 1. Pharmaceutical Expenditure structure under current forecast in 2020-2025



Policy Interventions	Calculation methodology	Pharma expenditure and clawback reduction (million €)				
Reimbursement - Volume		**2022**	**2023**	**2024**	**2025**	**Total**
Medium - Long run effect interventions						
Introduce Therapeutic/Prescribing Protocols for key therapeutic categories to rationalize treatment management	From literature review Protocols for 10 key therapeutic categories were identified. The protocols identified were applied to current practice to estimate spending decrease			60	60	120
Develop Patient Registries for key therapeutic categories to follow up on resources utilization, treatment outcomes and protocols' adherence	A literature review was conducted to identify spending decrease after the implementation of disease registries and the relevant impact was applied to current situation in Greece			50	60	110
Reduce the use of Antibiotics	The Nordics antibiotics protocols were used to estimate their implementation effect on current spending			30	30	60
Short run effect interventions						
Abolishment of the Retail and Reimbursement price equivalence for generic medicines	The official reimbursement price was applied to all generic medicines instead of the relevant retail price		70	40	40	150
Exclusion of no or low clinical benefit products from Positive list	EU positive lists were used to identify those drugs that can be transferred to the Negative/OTC list in Greece		10			10
Pharmacies dispense required treatment dosages according to SmPC & protocols	The categories that patients receive more packs/pills than required were identified and adjusted accordingly		5	5	5	15
Savings annually			**85**	**185**	**195**	**465**
Price - Volume		**2022**	**2023**	**2024**	**2025**	**Total**
Medium - Long run effect interventions						
Introduce the Horizon Scanning process for new therapies to identify potential savings	EU best practices was used to identify upcoming health technologies that increase budget and average innovation discount were applied			60	80	140
Short run effect interventions						
Closed Budgets for high-cost therapeutic categories or medicines	High-cost categories were identified and closed budgets with a discount were applied to equal paybacks	50	100	150	250	550
Annual Price Reassessment	Price decrease trends per drug category was calculated and applied to the annual reassessment scenario		20	20	20	60
Gx Repricing according to the average of the 2 lowest prices in EU19	2 EU lowest prices per each generic was identified and used to determine their relevant in Greece		50	40	40	130
Abolishment of the maximum 7% price decrease, during official prices reassessment	From PB the prices of the 2 lowest countries were used and the 7% price cap was removed		60	30	30	120
Abolishment of the minimum price of 0.2 euros Daily Treatment Cost	Prices of the previous PB were used & the price cap of 0.2€ per Daily Treatment Cost was removed		50	30	30	110
Quit referencing the 9-digit product code (EZ countries) during price reassessment	The rule of referencing the 9-digit product code was changed to include same formulation comparisons		25	10	10	45
Savings annually		**50**	**305**	**340**	**460**	**1155**
Total savings annually		**50**	**390**	**525**	**655**	**1620**

Figure 2. Pharmaceutical Market forecast 2022- 2025 if RRF will NOT be achieved

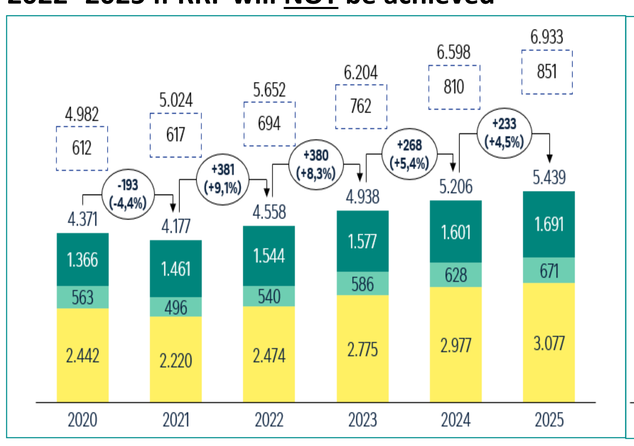


Figure 3. Pharmaceutical Market forecast 2022-2025 if RRF will be achieved

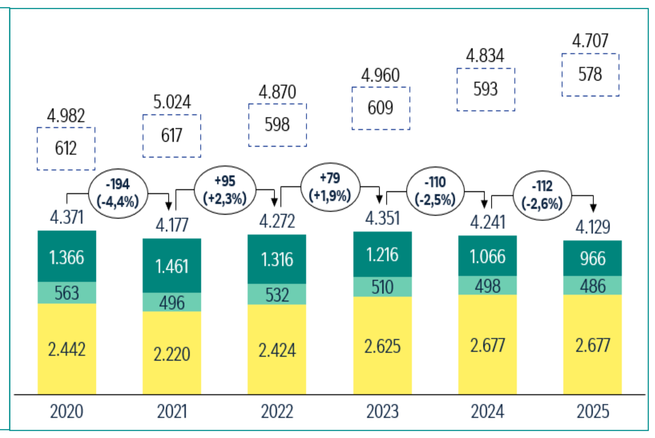
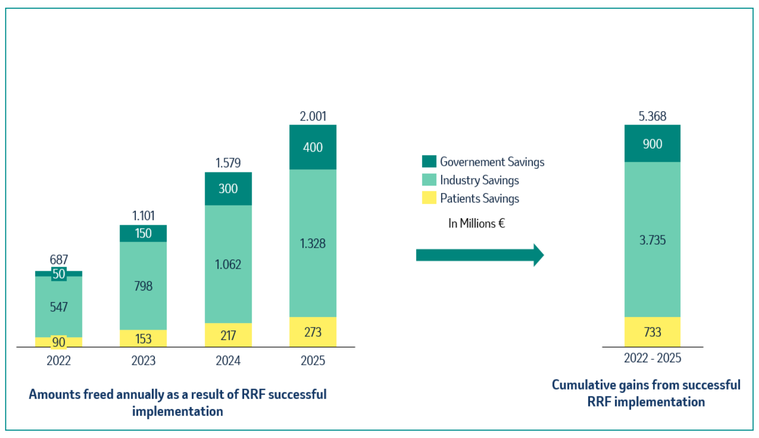


Figure 4. Impact of RRF Success to stakeholders and the economy



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