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Policy Briefs

on

Pharmaceutical Policy Interventions in Greece and their Impact

Pharmaceutical Sector Rebates and Paybacks in the Greek Healthcare Context: From Temporary Measure to Structural Distortion

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Abbreviations

CPCF	Community Pharmacy Contractual Framework
EOPYY	National Organization for the Provision of Health Services
FEK	Issue of the Official Gazette of the Hellenic Republic
GAO	United States General Accounting Office
GDP	Gross Domestic Product
GSG	Gesundheitsstrukturgesetz (German Health Structure Act)
HTA	Health Technology Assessment
IOBE	Foundation for Economic & Industrial Research (Greece)
KMES	Department of Prescription Processing and Control (EOPYY, Greece)
NHS	National Health Service (UK)
UK	United Kingdom

Introduction

Healthcare systems operating under a fixed medicines budget, often put in place mechanisms to recoup spending overruns in order to stay within budget (Mills and Kanavos, 2020). One such mechanism is a "payback", namely, a mandatory retrospective revenue return from pharmaceutical manufacturers to public payers, triggered when realized expenditure exceeds the predefined budget ceiling (Mills and Kanavos, 2020). Paybacks serve to reallocate part of the financial risk of deficit from the health system to the industry, thereby reinforcing budgetary discipline and neutralizing the fiscal impact of excessive spending on public funds (Mills and Kanavos, 2020).

One of the first instances of a legislated payback in Europe emerged in Germany with the 1993 Health Care Structure Act (Gesundheitsstrukturgesetz, GSG), which implemented a global budget for annual outpatient medicine spending, capped at 1991 levels (United States General Accounting Office, 1993). Crucially, the law stipulated that if the budget limit was exceeded, the overspend would be jointly recovered ("paid back") from physician budgets and pharmaceutical manufacturers through mandatory returns (United States General Accounting Office, 1993). This provision was unprecedented at the time, in that it placed direct statutory financial liability for cost overruns on healthcare professional associations operating at regional level (for a modest part of the overrun) and pharmaceutical manufacturers.

It is important to distinguish paybacks from other cost-containment measures, which entail mandatory transfers from the pharmaceutical industry to the public payer or social health insurance body, namely rebates[1] (Mills and Kanavos, 2020). Rebates consist in fixed prospective discounts on medicine prices, which are incident regardless of budget outcomes and – depending on their precise design and target – may be required for inclusion in the positive reimbursement list or linked to sales volume (Mills and Kanavos, 2020). Unlike rebates, paybacks are ex-post remedial tools tied directly to observed overspending above the set budget cap.[2]

[1] The first documented rebate in Europe was also in Germany with the 1993 Health Care Structure Act (Gesundheitsstrukturgesetz, GSG), which introduced a mandatory percentage discount (Zwangsrabatt) on the ex-factory price of all medicines reimbursed by social health insurance (SHI) (United States General Accounting Office, 1993). The policy was operationalized via pharmacies and insurance bodies: pharmacists deducted the rebate amount when billing the insurer and were then compensated by the manufacturer (United States General Accounting Office, 1993). In this way, funds flowed from the industry back to insurers for every reimbursed prescription.

[2] Rebates on ex-factory prices of medicines have been consistently employed in Greece over the last 15 years; however, their operation and evolution are beyond the scope of this brief.

In Greece, the mechanism known as "the clawback" is effectively a payback policy, as described earlier. Introduced in 2012 alongside the imposition of a capped public medicine budget (at 1.33% of GDP for that year) it was in line with the fiscal austerity mandate of the First Economic Adjustment Program for Greece (Yfantopoulos et al., 2016). The policy requires pharmaceutical companies to refund in full any excess amount of realized expenditure beyond the fixed budget ceiling in a defined channel (*e.g.*, outpatient or hospital) to the government. The refund obligation for each pharmaceutical company is calculated based on their relative market and/or sales growth in the given spending channel and paid back automatically on a 6-monthlys basis (Greek Government Gazette, 2012a).

It must be cautioned that the term "clawback" has been used variably across jurisdictions (Espín and Rovira, 2007). In the UK, it originally referred to regulatory deductions applied retrospectively to community pharmacies when their retained profit margins on reimbursed NHS medicines surpassed agreed thresholds, introduced by the Department of Health under the 2005 Community Pharmacy Contractual Framework (CPCF) in order to recover excess dispenser profit (National Audit Office, 2010). Nonetheless, in the context of pharmaceutical policy in Greece – and the present brief – "the clawback" refers to the explained payback obligation on pharmaceutical manufacturers to compensate public budget overruns.

The analysis that follows examines the rationale, implementation, and effects of the clawback in the Greek pharmaceutical system, and assesses the distortions it has given rise to over time.

Background

The "clawback" on pharmaceutical expenditure in Greece was introduced in March 2012, as an emergency response to the fiscal crisis (Greek Government Gazette, 2012b). It was originally intended as a temporary measure to ensure adherence to fixed public pharmaceutical budget caps, amounting to 1% of GDP (Yfantopoulos et al., 2016).

However, over the decade that ensued, the clawback evolved into a permanent structural component of the health financing system applied pervasively across all pharmaceutical spending channels (outpatient and hospital segments). Decision-makers' overreliance on the policy as a panacea to safeguard the available public funds institutionalized cost-shifting as the suggested 'solution' to uncontrolled growth in pharmaceutical spending, rather than addressing its underlying root causes, such as excessive pharmaceutical consumption and inefficiency in pricing and reimbursement.

Objective and Approach

This policy brief examines the legislative evolution of the clawback mechanism in Greece between 2012 and 2024, its impact on fiscal balance and sustainability in the financing of pharmaceutical expenditure, and, ultimately, the implications it has had on market dynamics and incentives for pharmaceutical manufacturers.

The legal framework on the application, operation and regulation of the clawback was identified and its evolution traced over the period from 2012 to 2024 through detailed review of all relevant legislation published in the Official Gazette of the Hellenic Republic during this period. Evidence on the magnitude of annual clawback in different medicine spending channels was drawn from public sources, such as the annual pharmaceutical market *Facts & Figures* reports by the Foundation for Economic & Industrial Research (IOBE), as well as EOPYY expenditure data made available through the Department of Prescription Processing and Control (KMES).

Legislative Review

Table 1 below summarizes the key legislative acts enacting key developments in the evolution of the "clawback" policy in the Greek pharmaceutical market between 2012 and 2024, the time of introduction and intervention content (**Table 1**).

Table 1: Overview and evolution of clawback legislation in the Greek pharmaceutical market, 2012-2024

Legislation Act	Date of Introduction	Description of Intervention
Law 4052	March 2012	Introduction of the clawback on expenditure for outpatient medicines
FEK B2243	August 2014	EOPYY assumes sole responsibility for the calculation of the clawback based on e-prescription data on the reimbursed dispensations of outpatient drugs during the given 6-month period under consideration
Law 4549 **Law 4753** **Law 4876**	June 2018 November 2020 December 2021	Successive extensions of the initial 3-year horizon of implementation for the clawback on outpatient medicines: until 2022 (Law 4549), then until 2024 (Law 4753), finally until 2025 (Law 4876)
Law 4346	November 2015	Clawback introduced on expenditure for hospital medicines
FEK B2254	June 2017	***Revision of the calculation methodology for outpatient clawback*** The '90/10 rule' adopted. This rule stated that each company's clawback amount would be determined on two indicators: first, 90% would be based on the company's final market share (formulated by the sum of spending on all products in their portfolio) in the total realized expenditure (outpatient); and second, 10% on the company's "growth share" for the year in question. Growth share was defined as the ratio of a company's sales growth against all companies' aggregate sales growth in a given year
FEK B4617	December 2017	Application of the '90/10 rule' to hospital clawback as well (as described for outpatient clawback in FEK B2254)
FEK B3710 **FEK B3746**	July 2022 July 2022	***Revision of clawback calculation methodology*** Payback amount due by each company is determined based solely on the company's final market share in the corresponding pharmaceutical spending (outpatient or hospital) for the given time period. This revision was implemented first on hospital clawback (FEK 3710) and shortly thereafter in outpatient clawback as well (FEK 3746)
Law 4931	May 2022	Tiered system of caps on the share of realized expenditure that can be requested as clawback was put in place for hospital drugs depending on their (hospital) price (i.e., minus the mandatory 5% rebate and excluding VAT). For hospital drugs priced up to €5, no clawback (0%) was to be levied, for drugs priced between €5 and €15, 20% could be the maximum clawback collected, and for drugs between €15 and €30, the maximum clawback could be 40% of the associated EOPYY expenditure
Law 5034	March 2023	Maximum clawback limit of 10% of the corresponding EOPYY spending item applied to outpatient medicines with DTC ≤ €0.2

Source: The authors from review of the Official Gazette of the Hellenic Republic, 2012-2024.

Results

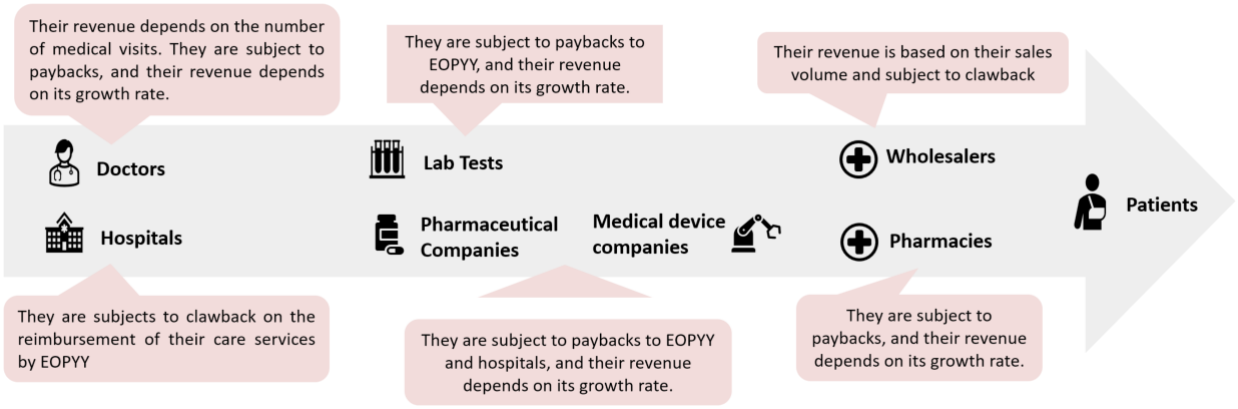
The clawback was originally introduced in March 2012 as a temporary measure on outpatient medicine spending to help ensure compliance of public expenditure in this channel with the budgetary limits that had been enforced (Greek Government Gazette, 2012b). Despite the initially intended short-term outlook, the clawback's horizon was repeatedly extended perpetuating its uninterrupted application up until today, while its scope was quickly expanded.

First, expenditure on hospital medicines also became subject to the clawback in 2015 (Greek Government Gazette, 2015), and gradually the instrument was implemented on spending for the full range of healthcare goods and services, including the reimbursement of medical devices, diagnostic and imaging laboratory tests, the remuneration of the healthcare workforce for service delivery in the public health system, and the payment of wholesalers and community pharmacies by EOPYY. The burden of the policy became incident on almost all agents in the health system, from pharmaceutical companies to practicing clinicians, public hospitals, medicine wholesalers and dispensing pharmacists.

Importantly, the legislated calculation methodology explicitly linked the total clawback amount due by each pharmaceutical company to EOPYY for spending on hospital or outpatient medicines, to the market share their product sales represented in the relevant channel in question and/or their sales growth rate (**Table 1**Table 1).

This dependency created and perpetuated strong distorted incentives for the sales – and, hence, consumption – volume of medicines to be continuously rising in Greece (**Error! Reference source not found.**), by the following mechanism: for the pharmaceutical manufacturer to safeguard against their annual net revenue shrinking in a given pharmaceutical channel (hospital or outpatient medicines), they needed to ensure an annual rate of sales growth at least as high as that of the possible clawback growth. Since the public budget practically remains fixed and stagnant year-on-year (bar modest infusions), the clawback is destined to grow at a higher rate than total expenditure in each channel. This implies that every company is incentivized to try to outpace the market growth rate every year in both outpatient and hospital medicines, just so as to maintain their net revenue. Similar reasoning accounts for the inflationary pressure and over-consumption motive that the clawback imposes on all other stakeholders in the national health system, including prescribing physicians, wholesalers and retail pharmacies (**Error! Reference source not found.**).

Figure 1: Application of payback across healthcare services and agents in the Greek market and distorted incentives to increase consumption

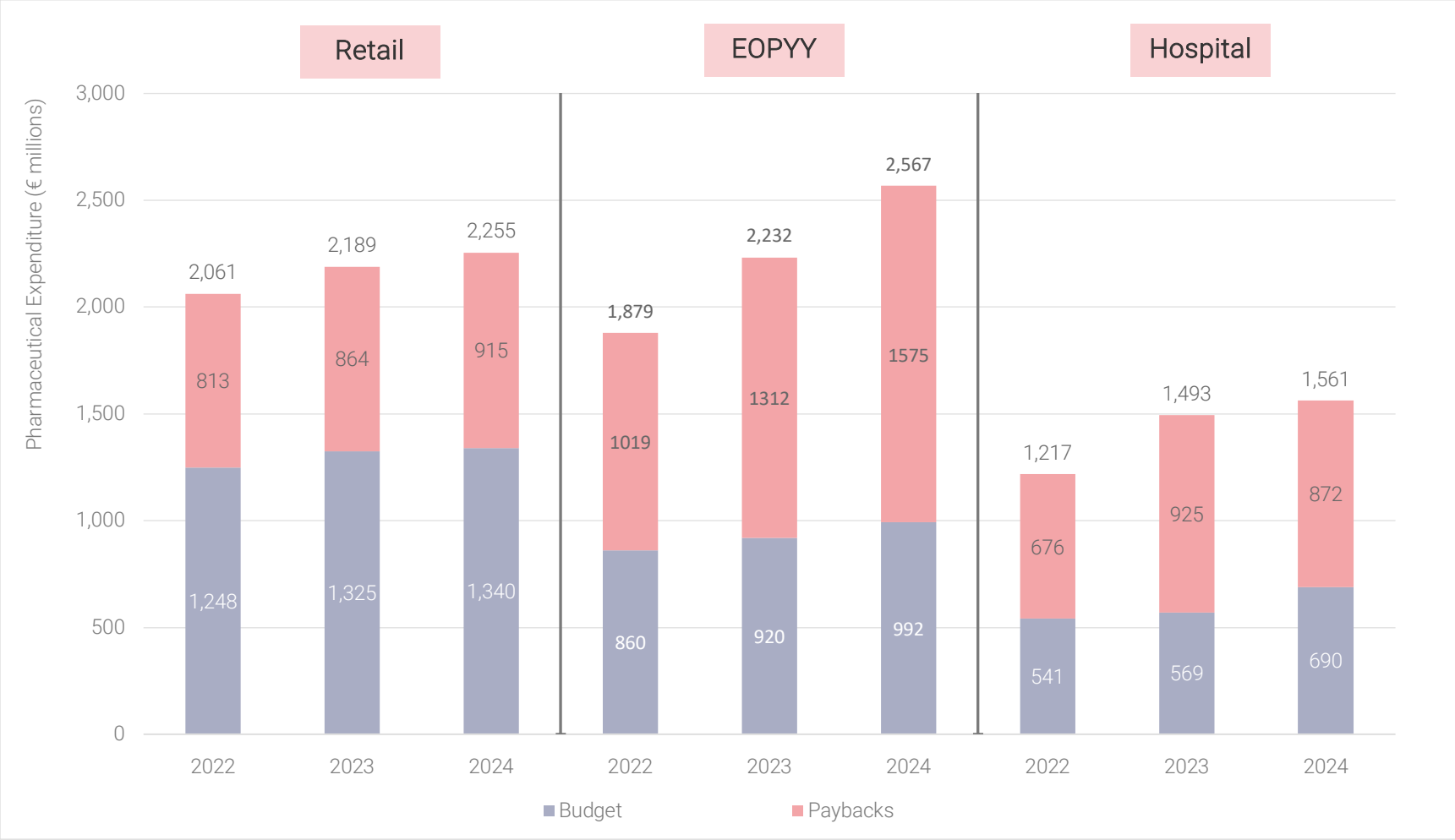


Source: The authors from review of the Official Gazette of the Hellenic Republic, 2012-2024

Consequently, not only has the application of the "clawback" failed to curtail the total pharmaceutical expenditure in Greece – which is to be anticipated since the measure is not designed to counteract growth in spending or consumption volume – but it has in fact facilitated its precipitous growth over the 2012 to 2024 period. In combination with the marginal increments of the public pharmaceutical budget, fixed at 1% of GDP, the result has been an increasingly disproportionate financing mix, whereby the national budget covers 48% of outlays and industry 52% (**Figure 2**).

In the retail pharmaceutical channel, the total expenditure that was covered by industry paybacks (*i.e.,* clawback and rebate) was equal to €813 million in 2022 and €915 million in 2024 (**Figure 2**). In terms of the relative share of the corresponding annual total, industry funding absorbed 39.5% of retail pharmaceutical expenditure in 2022 and 40.5% in 2024. Similarly, with respect to the EOPYY channel, pharmaceutical companies were already rebating 54% of total expenditure in 2022, representing €1,019 million (**Figure 2**). This was higher – by almost €160 million – than the amount of spending ultimately borne by EOPYY for the year (€860 million). In view of the payer's fixed budget ceiling, increasing marginally year-on-year, this disparity grew to approximately €583 million in 2024. Overall, industry returns amounted to 61% of the total spending of EOPYY on medicines for the year. Finally, for the hospital channel, the industry contribution was €676 million in 2022, eclipsing the total public financing of €541 million for the year, and €872 million in 2024, consistently representing 55% of the total annual expenditure burden (**Figure 2**).

Figure 2: Breakdown of pharmaceutical expenditure across distribution channels by public budget and industry paybacks, 2022 – 2024



Source: (Foundation for Economic & Industrial Research (IOBE), 2025), (EOPYY, 2025).

Discussion and Implications

The development and extensive use of the clawback mechanism reflects a growing divergence between Greece's pharmaceutical policy practice and the principles of a rational sustainability-oriented framework. Rather than aiming to achieve fiscal balance through prospective management and rationalization of pharmaceutical spending, decision-makers have relied on cost recovery and turned an ad hoc short-term intervention to a 'one-size-fits-all' solution deployed far beyond its intended scope and time horizon. Importantly, volume has remained uncontrolled during this period.

This highlights a lack of strategic vision and neglect of long-term system needs and objectives on the part of government authorities and regulators. In terms of operationalization of the measure, the linkage of clawback liabilities to market share has generated incentives for continuous expansion in sales volume for pharmaceutical companies in both the outpatient and hospital medicine segments – aggravating the very driving force of the problem that it was supposed to address.

This status quo is clearly unsustainable. The overlooked policy lever to pivot away from cost-shifting and begin to effectively counteract the perennial increase in total pharmaceutical spending is volume control. This could be achieved through demand-side interventions promoting rational use of medicines, such as mandatory prescribing guidance development and implementation, as well as reinforcement of value-based reimbursement recommendations through HTA. Demand-side control, however, done through rational prescribing and continuous and real-time monitoring, is likely to deliver over the medium-term, therefore, any interventions on that front will have to co-exist with clawback arrangements. Consequently, the route to rational and evidence-based care will require political determination and meticulous implementation.

Next Steps

The clawback mechanism, as currently applied, functions as a horizontal, ex-post cost-recovery tool that makes no distinction between pharmaceutical product categories and lends no consideration to additional therapeutic value, or clinical necessity. Its across-the-board design discourages investment and distorts incentives on the market, while failing to address the structural drivers of excess spending – uncontrolled volume and inefficiency in resource use.

Moving forward, a shift is needed toward a proactive, evidence-driven approach to pharmaceutical expenditure management that emphasizes rational resource allocation

rather than retrospective correction. To that end, the authorities need to re-focus on managing the available resources/budget rather than managing and distributing the excess. For new therapies, central to this transition is the systematic incorporation of value-based criteria into reimbursement decision-making, including the recommendation of subpopulation-level restrictions in the reimbursement of new therapies by the HTA Committee, as and when supported by clinical evidence and cost-effectiveness results against relevant comparators for the Greek healthcare system. This approach is already standard practice in mature HTA systems, where restricting use of new treatments to a defined patient subgroup or a specific circumstance (*e.g.,* particular line of therapy or only upon unsuitability of preferred alternatives) within the perimeter of the approved indication serves to maximise therapeutic value-for-money and mitigate the impact of clinical or economic uncertainties (Therianos et al., 2025). For older medicines, higher uptake and use of generics/generic brands, which can be procured at lower cost, can offer additional fiscal relief.

Refocusing policy strategy toward targeted, forward-looking demand-side interventions will be critical to improving predictability and enhancing efficiency of realized pharmaceutical spending – developments which will serve to mitigate fiscal pressure on the public budget by virtue of ex-ante cost-containment and reduction of potentially wasteful expenditure. In this way, the aim is to curtail reliance on paybacks while maintaining control of budget deficit risk, enabling progressive scale-back of the clawback mechanism to rebalance the pharmaceutical financing mix between state and industry contributions while reducing dis-incentives across all industry players (foreign and domestic) to engage in the Greek market.

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