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Policy Briefs on Pharmaceutical Policy Interventions in Greece and their Impact

External Reference Pricing (ERP) as a Cost Containment Measure

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Abbreviations

ATC	Anatomical Therapeutic Chemical (classification system)
EOF	National Medicines Agency (Greece)
EOPYY	National Organization for the Provision of Health Services (Greece)
ERP	External Reference Pricing
EU	European Union
FEK	Issue of the Official Gazette of the Hellenic Republic (Greece)
IOBE	Foundation for Economic & Industrial Research (Greece)
KMES	Department of Prescription Processing and Control (EOPYY)
LoE	Loss of Exclusivity (patent expiry)
OECD	Organisation for Economic Co-operation and Development

Introduction

External Reference Pricing (ERP) is a price-setting mechanism whereby a country determines the domestic prices of (predominantly) new medicines by benchmarking against prices in a selected set of comparator countries (Vogler and Zimmermann, 2013). International evidence shows that ERP systems function most effectively when they abide by a set of recognised best-practice principles: (a) clear alignment with health-system objectives; (b) transparent administrative rules; (c) consistent criteria for basket selection; (d) reliance on publicly available ex-factory prices; (e) use of average-based calculations; (f) appropriate (and, ideally, limited) frequency of price revisions; and (g) mechanisms to minimise distortions arising from exchange rates (Kanavos et al., 2017). These principles, taken together, define an ERP framework that is stable, predictable, and methodologically coherent (Kanavos et al., 2017).

Against the above, ERP has been shown to be associated with launch and access delays as well as launch sequencing and a large number of variations exist across settings (Kanavos et al, 2020). Its practical importance and overall usefulness, however, has declined over the past 15 years or so because list prices that are reported and countries take into account are significantly different from transaction prices, which are negotiated between manufacturers and health care systems.

In Greece, ERP has been employed in direct price-setting capacity as the main instrument of regulation of domestic ex-factory prices of medicines since 2010, in the aim of cost-containment and expenditure control – consistent with its use internationally (Economou, 2010). The system draws price data from the basket comprising all Eurozone Member-States and calculates domestic prices based on the average of the 2 lowest ex-factory prices in the basket (Greek Government Gazette, 2019a). Importantly, the matching of each drug with its reference product in different national contexts is governed by the 9-digit identifier code assigned by the Greek National Medicines Agency (EOF), which – by design – captures the full set of characteristics that define the "same put-up", namely, active ingredient, pharmaceutical form, strength and packaging (Greek Government Gazette, 2015). Since 2015, legislation has required that ERP comparisons be conducted exclusively between products sharing identical attributes as encoded in this 9-digit EOF code, thereby mandating strict like-for-like comparability across jurisdictions for price referencing (Greek Government Gazette, 2015). In itself, this is a limiting condition, but is not the only one in the Greek ERP system.

Price revision on all pharmaceutical products takes place annually in Greece (Greek Government Gazette, 2018). However, the introduction of a 7% ceiling on downward price adjustments between successive price revisions in November 2019 (Greek Government Gazette, 2019b), has limited the system's capacity to transmit international price declines into the Greek market. This cap compromises the functioning of ERP as a cost containment

mechanism, reducing responsiveness to price signals from reference countries and leading to downward price rigidity.

Background

Rational pharmaceutical policy thinking postulates that pricing mechanisms should promote efficiency, transparency, and responsiveness to evidence on value and cost-effectiveness. In Greece, since 2010, ERP has been the main tool used for the determination of domestic ex-factory prices of medicines (Economou, 2010). The premise of ERP methodology rests on taking advantage of the lowest prices achieved across reference countries to enact a similarly low domestic price for the medicine in question and improve affordability for the national payer.

The introduction of a 7% cap on price reductions allowed at successive repricing rounds on on-patent, off-patent and generic medicines has contradicted and undermined this exact principle of ERP operation. Since November 2019, the intervention has maintained domestic pharmaceutical prices at higher levels on average than they would have declined to in line with ERP calculations, reducing the effectiveness of ERP in the Greek market and introducing distortions.

Objective and Approach

This policy brief analyses the policy rationale, implementation and impact of the 7% price reduction ceiling in the context of Greece's ERP system with respect to the overarching objective of cost-containment and efficiency in pharmaceutical spending.

A review of relevant pharmaceutical pricing legislation published in the Official Gazette of the Hellenic Republic from 2010 to 2024 was conducted. Further, quantitative data tracking the price trajectories of medicines on the positive list over the period between 2019 and 2023 was extracted from the official price bulletins released by the Ministry of Health. Data on the annual pharmaceutical expenditure registered in 2023 in 9 different ATC1 categories across the retail, hospital and EOPYY channels was sourced from EOPYY's Department of Prescription Processing and Control (KMES) as well as published estimates by the Foundation for Economic & Industrial Research (IOBE). Simulation modelling was employed to estimate the potential savings in pharmaceutical spending which might have accrued if prices of medicines had been allowed to evolve as dictated by the ERP methodology between 2019 and 2023 in the absence of the 7% cap on price reduction at each iteration of repricing.

Legislative Review

The 7% cap on the price reduction a given drug could undergo between successive iterations of repricing was implemented in November 2019 by way of Law 4638 across on-patent, off-patent and generic medicines (**Table 1**) (Greek Government Gazette, 2019b). A more detailed overview of pricing regulations covering the 2010-2024 period, is provided in Appendix Table. Concurrent ERP legislation dictated that on-patent and off-patent originators in Greece were priced at the average of the 2 lowest prices in the Eurozone (Greek Government Gazette, 2019a). Generic medicines were priced at 65% of the off-patent originator price, if that existed in the domestic market. Otherwise, their price was determined based on an appropriate reference product identified in EU countries, or similar generics already available in Greece (Greek Government Gazette, 2019c). This set of laws regulating prices of on-patent, off-patent and generic drugs continues to apply.

Prior to the establishment of the 7% cap, a 10% cap had already been introduced in March 2019 (Greek Government Gazette, 2019a). Nevertheless, due to its short-lived application and replacement less than 9 months later by the 7% mark, we have focused on the latter, which has since remained in force without any interruption or further adjustment.

Table 1: Legislative Review on ERP regulation and the price reduction cap

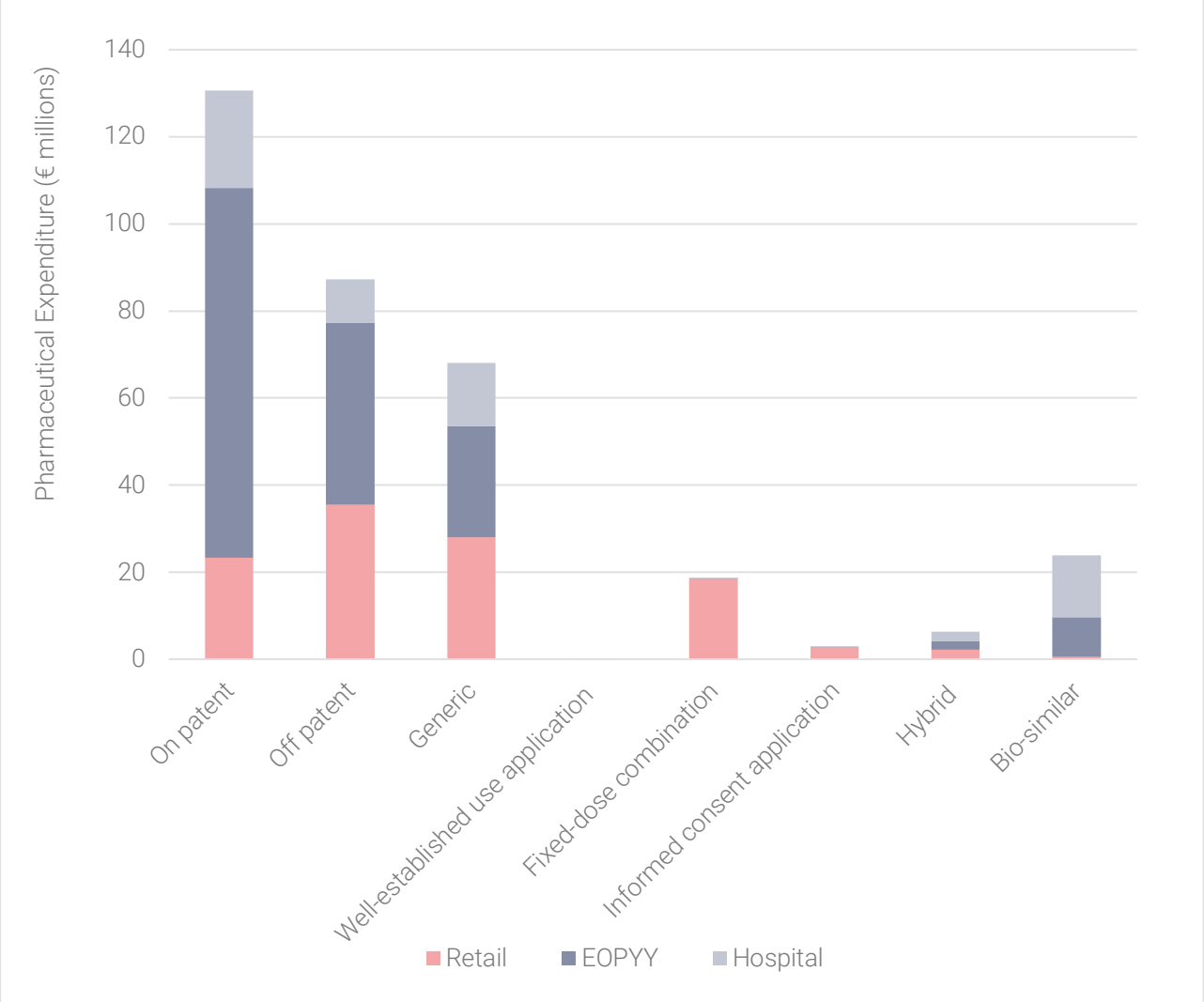
Legislation Act	Date of Introduction	Description of Intervention
Law 4213	December 2013	Ex-factory price of generics set at (maximum) 65% of the price of the respective off-patent originator.
Law 4600	March 2019	Ex-factory price of on-patent medicines calculated as the average of the 2 lowest (unequal) prices among Eurozone countries. Ex-factory price of off-patent originators calculated as the average of the 2 lowest (unequal) prices among Eurozone countries. Maximum cap of 10% price reduction between successive repricing rounds applied to on-patent and off-patent medicines.
Law 4638	November 2019	Cap on maximum price reduction allowed at each round of repricing set at 7% (lowered from 10%) for on-patent, off-patent and generic medicines.

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

Results

For 2023, the estimated magnitude of the potential savings that could have been achieved if the 7% cap in each spending channel (retail, EOPYY and hospital) across different categories of medicines had not been implemented is shown in Figure 1**Figure 1.** Medicines have been categorised in accordance with their "legal basis" of approval into the following groups: (a) on-patent originators; (b) off-patent originators; (c) generics; (d) fixed dose combinations; (e) informed consent applications; (f) hybrid medicines; (g) biosimilars; and (h) well-established use applications.

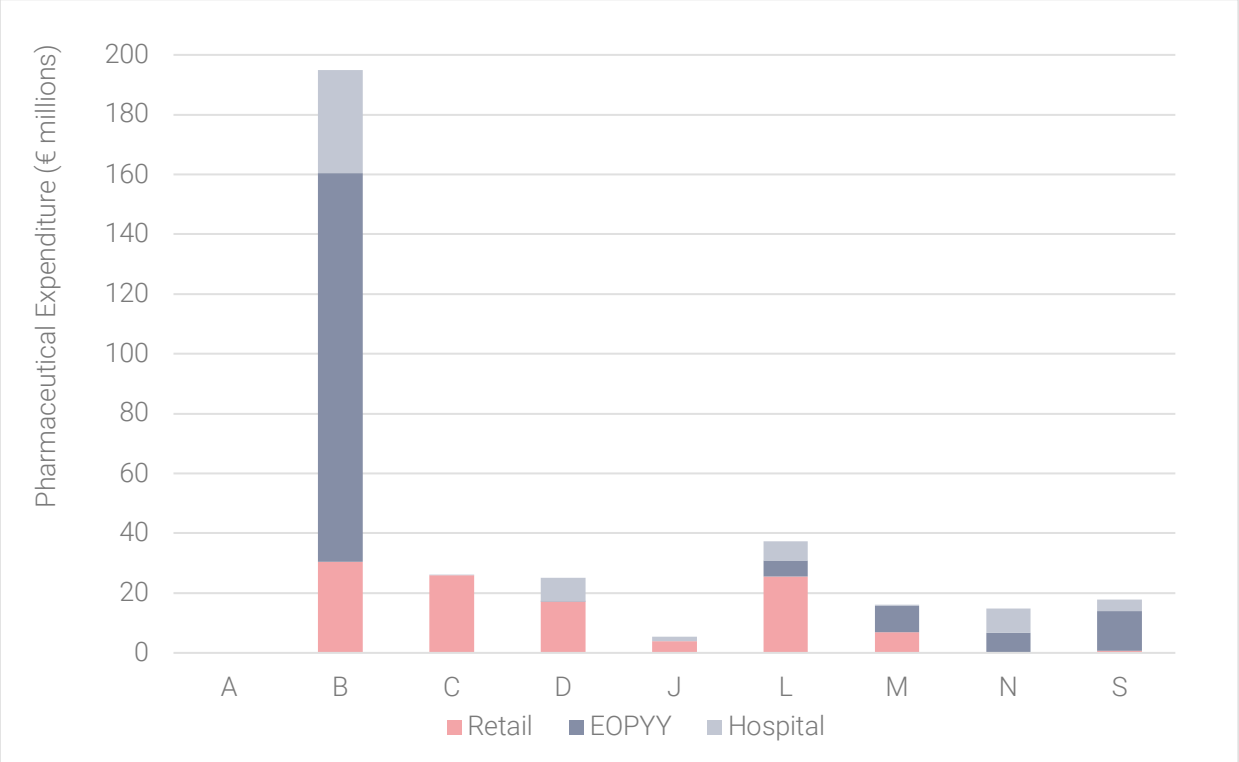
Figure 1: The 7% price reduction cap on repricing: Potential savings identified by drug category as per their legal basis1 and distribution channel, 2023



Source: (Foundation for Economic & Industrial Research (IOBE), 2023), (EOPYY, 2025), (OECD Data Explorer, 2025).

Potential savings amounting to €130.7 million on expenditure for on-patent medicines could have been realized in 2023 if the 7% cap had not been implemented. Nearly two thirds of these (65%) would have accrued in spending associated with on-patent drugs reimbursed by EOPYY. The second largest potential saving in 2023 could have been in off-patent originators, estimated at approximately €87.2 million. Of this amount, approximately 41% would have benefited the retail channel and 48% the EOPYY channel. Sizeable savings could have been secured in the generic and biosimilar segments of the market, equal to €68 million and €23.8 million, respectively. Across all categories of pharmaceuticals based on their legal basis of approval, the total amount that the 7% ceiling on price reduction cost the Greek health system, in terms of potential savings in 2023 was estimated to be €337 million.

Figure 2: The 7% price reduction cap on repricing: potential savings by ATC1 category and distribution channel, 2023



Source: (Foundation for Economic & Industrial Research (IOBE), 2023), (EOPYY, 2025).

ATC-1 Categories Legend

A – Alimentary tract and metabolism

B – Blood and blood forming organs

C – Cardiovascular system

D – Dermatologicals

J – Anti-infectives for systemic use

L – Antineoplastic and immunomodulating agents

M – Musculo-skeletal system

N – Nervous system

S – Sensory Organs

Investigating the impact of the policy per ATC1 category in the Greek positive list (**Figure 2**), it appears that for the year 2023, expenditure on blood and blood forming organs (category B) was most impacted. The specific ATC1 category includes, among others, antihemorrhagics and antithrombotic agents, such as vitamin K antagonists and heparins. Spending on this group might have been €194.9 million lower, *ceteris paribus*, in the absence of the 7% cap. Important savings were also estimated in antineoplastic and immunomodulating agents (ATC "L") (€37.4 million), in cardiovascular diseases (ATC "C") (€26.0 million) and skin diseases (ATC "D") (€25.1 million).

Discussion and Implications

This analysis, although static in nature, was conducted in order to showcase the effect of not exploiting in full the extent of a price-setting mechanism, such as ERP. It suggests that a command and control regulatory tool has been calibrated to under-perform in order to keep list prices at an artificially higher level than what would otherwise be the case. As list prices are the starting point for negotiation, this measure could also affect net prices. From a dynamic perspective, it should be recognised that despite the caveats in list price setting due to the price reduction cap, other mechanisms have been put in place to mitigate these effects and, specifically, the rebate and payback policy, affecting net prices of products reimbursed by the health system. The impact on the out-of-pocket segment, however, could be considerable.

In countries where ERP is implemented as the main form of pricing setting, one of its cornerstones is the possibility of frequent price revisions to enable price reductions secured via similar mechanisms in reference countries and reflect these to the domestic market as soon and as regularly as possible (Kanavos et al., 2020). Regardless of whether frequent price revisions are an optimal policy, they nevertheless counterbalance the effect of launch sequencing by including lower price countries into the domestic basket.

In view of the above, capping price decreases at every round of repricing is a straightforward example of a measure operating against the wider policy framework it was incorporated in – the ERP rule governing (predominantly) on-patent and off-patent originator medicines in Greece. By disconnecting the alignment of domestic price to the lowest international comparators, the 7% cap limit effectively prevents the Greek healthcare system from benefiting from lower list prices and the savings that would have otherwise been secured, if these list prices were actually reimbursed. In complete opposition to the mandate and stated pressing need for cost minimization in pharmaceutical spending, the policy entrenches rigidity and hampers prices in Greece from declining as much and as fast as they would *ceteris paribus* in line with the spirit of ERP.

A return to unconstrained ERP adjustments across on-patent, off-patent and generic products, supported by transparent data and periodic review, would realign the system with the principles of efficiency and sustainability central to rational pharmaceutical pricing policy.

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Appendix Table: Legislative review on price regulation affecting originator & generic medicines, including ERP and the price reduction cap, 2010-2024.

Legislation Act	Date of Introduction	Description of Intervention
Law 3840	March 2010	Price of originator medicines reduced by at least 20% upon Loss-of-Exclusivity (LoE).
FEK B1231 **FEK B2785** **FEK B2719**	June 2011 December 2011 October 2012	Price reduction on originator medicines upon LoE increased to at least: 30% (June 2011), 35% (December 2011) and ultimately 50% (October 2012) of the last on-patent price.
FEK B2719	October 2012	Wholesale price of generic medicines set at 40% of the last on-patent price of the respective originator before its LoE.
FEK B545	March 2012	Ex-factory price of on-patent medicines calculated as the average of the 3 lowest prices observed in EU member-states.
Law 4213	December 2013	If a generic alternative was available in the Greek market, price of the originator decreased to 50% of the last on-patent price upon LoE, or set as equal to the average of the 3 lowest prices across EU countries (whichever method yielded the lowest resulting price). If no generic was sold domestically, price of the originator upon LoE determined by the latter method. Ex-factory price ceiling for generic medicines set at 65% of the price of the respective off-patent originator.
FEK B1958	September 2015	Mandated matching of each drug with its reference product in other countries for ERP based on the 9-digit EOF code defining the "same put-up": same active ingredient, pharmaceutical form, strength and packaging. Change (reduction) in the price of off-patent originators no longer incident immediately upon LoE-patent expiry, but only after entry of the first generic in the Greek market.
Law 4600	March 2019	Ex-factory price of on-patent medicines calculated as the average of the 2 lowest (unequal) prices among Eurozone countries. Ex-factory price of off-patent originator medicines calculated as the average of the 2 lowest (unequal) prices in Eurozone countries (no longer any provision for mandatory percentage reduction upon LoE). Maximum cap of 10% price reduction between successive repricing rounds applied to on-patent and off-patent medicines.
Law 4638	November 2019	Cap on maximum price reduction allowed at each round of repricing set at 7% (lowered from 10%) for on-patent, off-patent and generic medicines.

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

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