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Policy Briefs on Pharmaceutical Policy Interventions in Greece and their Impact

Exceptional Procurement Mechanisms: The IFET Channel in Greek Pharmaceutical Policy

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Abbreviations

EAS	Early Access Scheme(s)
EFPIA	European Federation of Pharmaceutical Industries and Associations
EODY	National Public Health Organization
EOF	National Medicines Agency
EPAS	Electronic Pre-Approval System
IFET	Institute of Pharmaceutical Research and Technology
IOBE	Foundation for Economic & Industrial Research
KMES	Department of Prescription Processing and Control
MA	Marketing Authorization
MAH	Marketing Authorization Holder(s)

Introduction

Health systems often employ exceptional pharmaceutical procurement mechanisms to enable patient access to medicines outside their standard regulatory and reimbursement frameworks. These mechanisms are designed to address circumstances of public health emergency, product shortages, or access gaps for medicines not approved or marketed domestically for which there is medical need. In the last case, exceptional procurement mechanisms include Early Access Schemes (EAS) which make medicines available to a limited number of patients either prior to marketing authorization in the given jurisdiction or before a reimbursement decision by the public payer (EFPIA, 2022). EAS may involve compassionate use or named-patients programs; the former supply groups of patients (e.g., a cohort with a specific condition or receiving treatment at a specific facility), whereas the latter operate on a case-by-case basis with physicians requesting access to unauthorized or uncovered treatment for an individual patient under their care – subject to regulatory approval and supervision (European Medicines Agency, 2010).

Across countries, exceptional mechanisms are invoked in high-need situations, including rare, severe or life-threatening diseases without satisfactory authorized treatment alternatives, innovative or highly expensive treatments not marketed domestically, or medicines facing supply disruptions (European Medicines Agency, 2010). Furthermore, they are limited in duration and scale, often terminating as soon as the pharmaceutical product gains formal regulatory approval or is awarded coverage under public health insurance (Chapman et al., 2023). In that, they serve as temporary exceptions to routine reimbursement and market entry procedures, aiming to bridge the access gaps, but ultimately complement – rather than replacing – the standard HTA, pricing and listing pathway.

In Greece, the Institute of Pharmaceutical Research and Technology (IFET) fulfils this role by procuring and distributing non-marketed medicines, subject to authorization by the National Medicines Agency (EOF) (IFET, 2025a). While originally conceived as a narrowly defined access channel to safeguard continuity of care and facilitate access to rare disease /high need drugs commercially unavailable in the domestic market, IFET has increasingly operated as a parallel reimbursement stream to the regular HTA appraisal and negotiation process for listing in Greece – raising questions about its scope, governance, and fiscal sustainability. This brief examines IFET's expanded operational footprint and its implications for pharmaceutical expenditure control and system coherence.

Background

Rational pharmaceutical policy thinking suggests that exceptional procurement mechanisms are in place to address supply disruptions and unmet medical need without replacing standard market channels. The Institute of Pharmaceutical Research and Technology (IFET) was originally conceived as precisely such a mechanism in Greece. Over time, however, its remit expanded from the intended mission of emergency importation to a broader procurement scope, often overlapping with routine reimbursement and distribution channels. This expansion has generated escalating expenditure by IFET and contributes to fiscal distortions across the pharmaceutical sector.

Objective and Approach

The objective of this brief is, first, to comment on the evolution of IFET's regulatory framework and expenditure dynamics during the period from 2012 to 2024; and, second, to examine the degree to which its current operations align with the principles of rational pharmaceutical policy — macro-level efficiency, transparency, and policy coherence.

The brief draws upon legislative sources (2012–2024), IFET's own resources on the Institute's profile, mission statement, objectives and publicly available annual financial reports, and secondary data on EOPYY pharmaceutical expenditure derived from the Department of Prescription Processing and Control (KMES). Quantitative analysis traces IFET spending trends, while review of published IFET import lists enables the examination of the therapeutic area and market availability status of products purchased and distributed by the Institute. Comparative analysis of IFET spending patterns with the evolution of total pharmaceutical expenditure and clawback burden provides insight into systemic interactions and fiscal spillovers.

Legislation Review

IFET is a subsidiary of the National Medicines Agency (EOF) and functions as the state's dedicated mechanism for ensuring access – by importation and domestic distribution – to pharmaceutical products deemed essential for the treatment of patients and the protection of public health, which are unavailable through regular market channels in Greece (IFET, 2025a). In principle, IFET's role is complementary to that of private-sector distributors, filling temporary supply gaps and maintaining emergency stocks under the supervision of EOF, the Ministry of Health, and the National Public Health Organization (EODY) (IFET, 2025a).

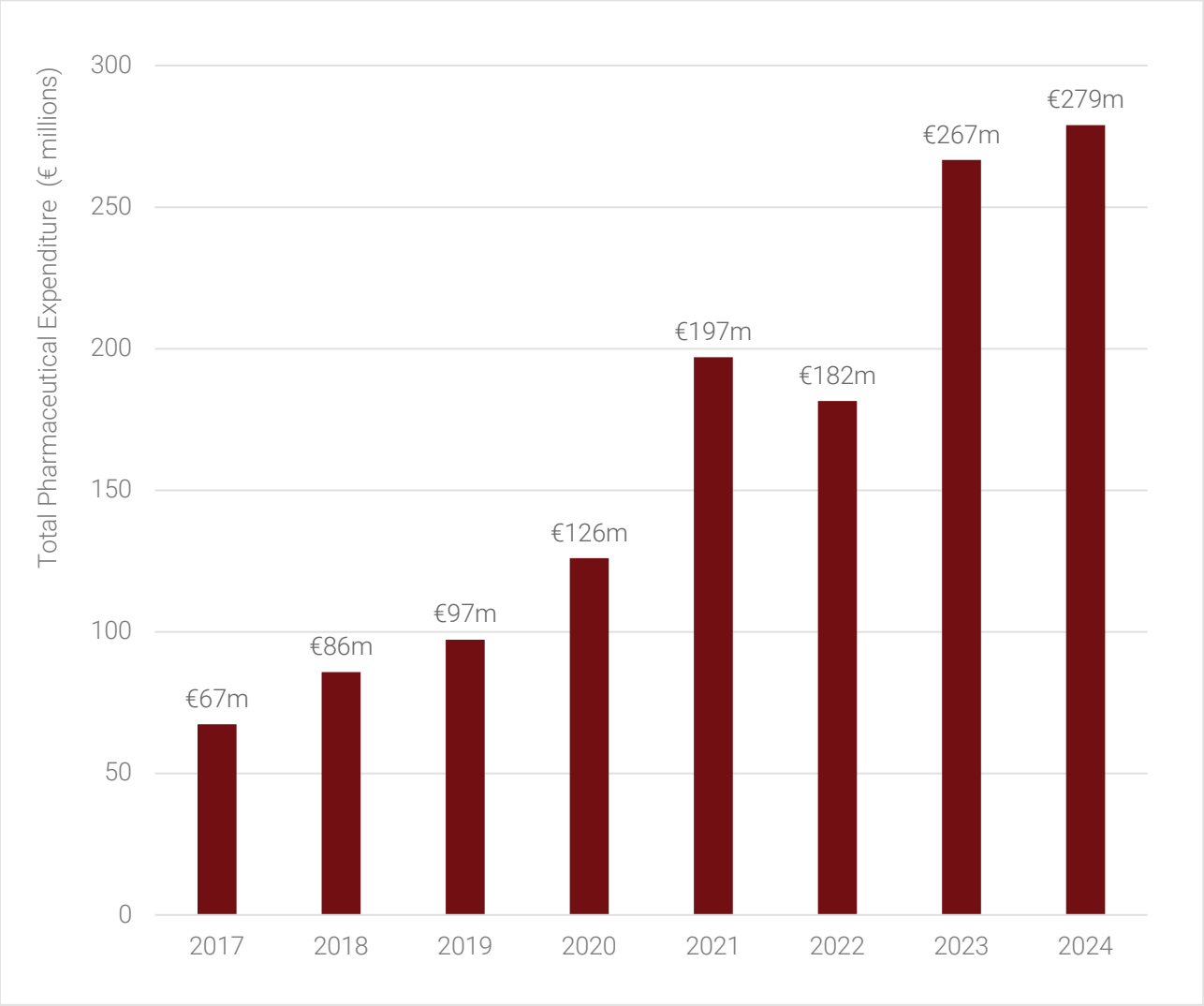
The products purchased and distributed by IFET are classified into three main categories. First, *permanent and emergency coverage medicines* imported to replenish safety stocks and address shortages in hospitals, warehouses, or EOPYY (IFET, 2025b). Second, *special hospital coverage medicines* procured upon hospital request to meet individualized treatment needs when suitable alternatives are unavailable in the local market (IFET, 2025b); these products must hold marketing authorization (MA) in the EU, EEA, or the United States - they may either possess MA in Greece but have not been marketed, not have MA in Greece or recently been authorized but have yet to receive a price (National Medicines Agency (EOF), 2020). Special hospital coverage orders require justification and approval by the attending physician and hospital scientific committee (National Medicines Agency (EOF), 2020). Third, *individual pharmacy orders* covering medicines not marketed in Greece but prescribed for specific patients through EOPYY or private pharmacies, subject to prior approval via the Electronic Pre-Approval System (EPAS).

Results

Despite the framework outlined above encompassing the medicines theoretically eligible to be procured via IFET, current practice has diverged from the intended remit. Based on recent evidence, IFET additionally purchased and distributed (a) products pending EMA approval, (b) products which had not been submitted for price approval for extended periods of time, (c) products which were (and are) included in EOPYY closed budgets, or the Positive List, and (d) products for which more than a year has lapsed since MA by EMA (IFET, 2025c).

This deviation may explain, at least in part, the evolution of the Institute's expenditure over time. Specifically, between 2017 and 2024, IFET expenditure rose from €67 million to over €279 million – a fourfold increase (**Figure 1**). Review of IFET product order lists indicates that a substantial portion of this spending concerns medicines already approved or reimbursable through standard EOPYY processes.

Figure 1: Total annual pharmaceutical expenditure on IFET purchases, 2017 – 2024



Source: IFET Annual Financial Statements, 2017 – 2024.

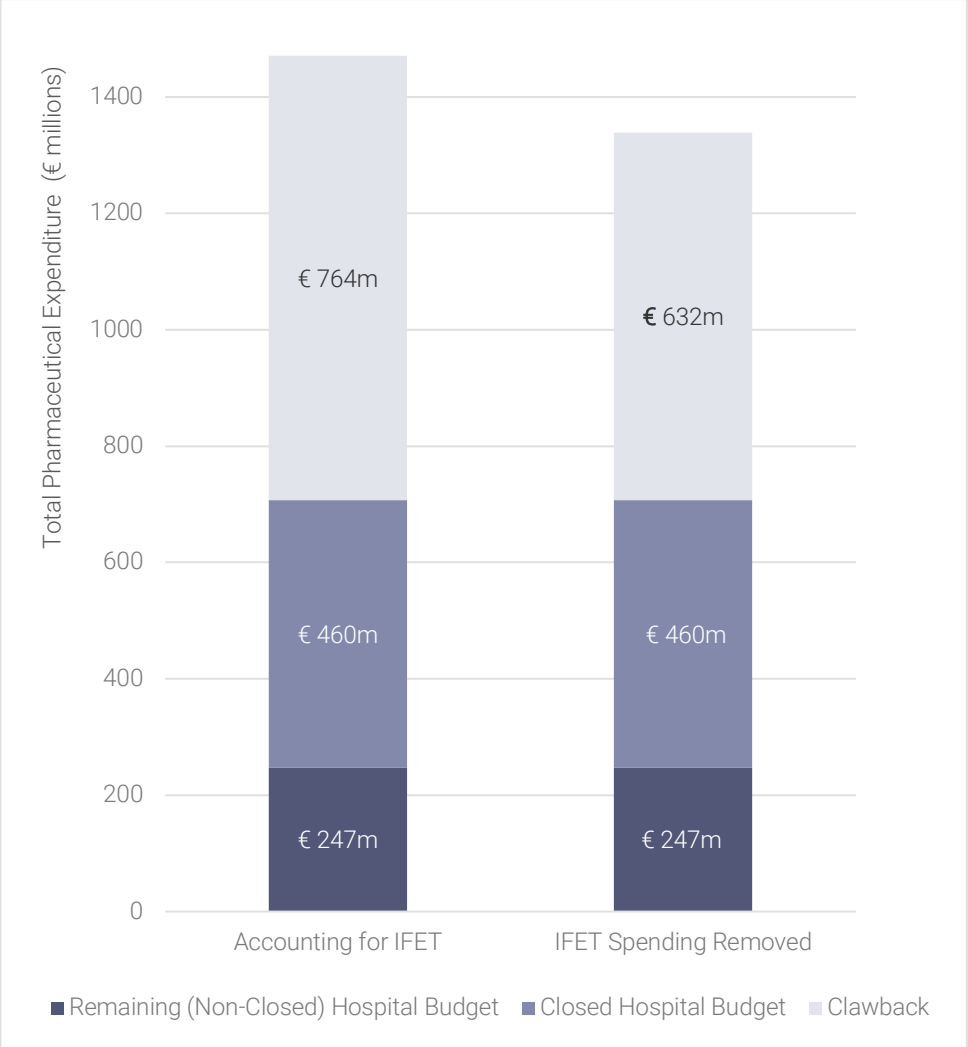
An important and attractive feature of this channel is that sales of medicines through IFET are exempt from direct clawback obligations on Marketing Authorization Holders (MAH's), are but counted towards total pharmaceutical spending in the respective channel (outpatient or hospital). As a result, they inflate the residual clawback burden on industry as a whole.

This creates a fiscal asymmetry, increasing the overall clawback amount due while redistributing the additional burden owing to IFET purchases across all pharmaceutical manufacturers – not only those with products imported through IFET during the year in question, but equally those operating exclusively in regular reimbursement channels. The result is a distorted incentive structure: the larger IFET's spending becomes, the higher the clawback rate applied to non-IFET products. This, manufacturers face escalating payback

liabilities for expenditure they did not generate, while those whose products are distributed through IFET benefit from partial cross-subsidization of their clawback dues. In turn, this encourages market actors to pursue importation via this channel as a strategy to mitigate clawback exposure, further expanding IFET's footprint and compounding the distortion.

Empirical evidence from 2024 demonstrates the magnitude of clawback impact. In the hospital channel, the total payback to government reached €764 million (Foundation for Economic & Industrial Research (IOBE), 2025). If the spending associated with IFET purchases were excluded, the clawback would decline to an estimated €632 million (**Figure 2**). IFET's inclusion in the expenditure baseline increased the effective payback rate from 47% to 52% of total hospital pharmaceutical spending in 2024.

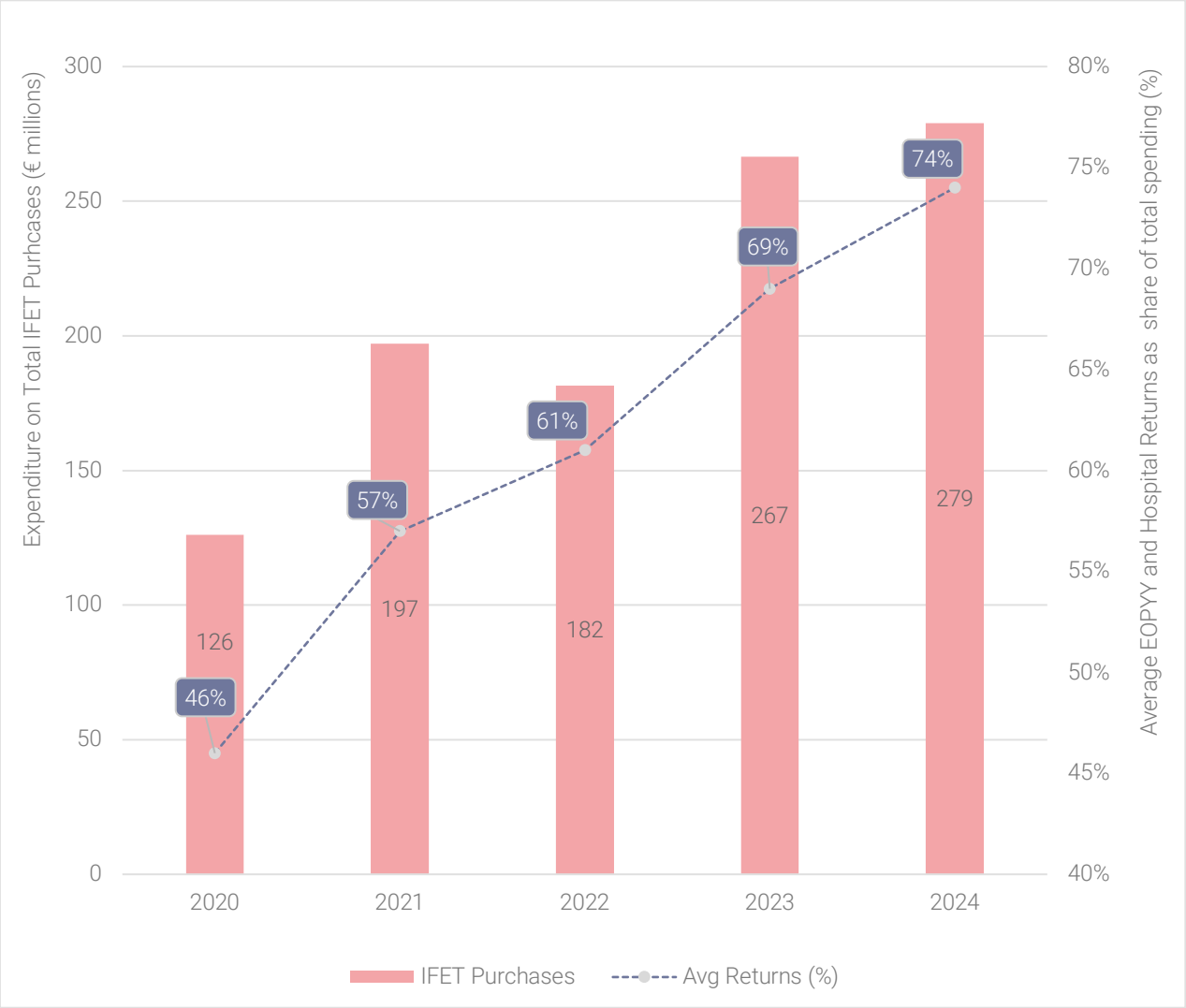
Figure 2: Impact of IFET purchases on pharmaceutical expenditure for hospital medicines, broken down by public budget and clawback (2024)



Source: (IFET, 2024), (Foundation for Economic & Industrial Research (IOBE), 2025)

The broader trend reinforces this dynamic. As IFET's annual expenditure more than doubled—from €126 million in 2020 to €279 million in 2024—the average proportion of total drug spending covered by industry paybacks in the hospital and EOPYY channels rose from 46% to 74% (**Figure 3**). This pattern suggests a consistent positive correlation between IFET's unregulated spending growth and the escalating fiscal burden on the wider pharmaceutical market.

Figure 3: Correlation between spending on IFET purchases and average returns (paaybacks) as a percentage of total expenditure in the EOPYY and hospital channels, 2020-2024



Source: IFET Annual Financial Statements, 2020 – 2024, (Foundation for Economic & Industrial Research (IOBE), 2025).

This feedback loop has transformed IFET from a targeted safety-net mechanism into an alternative route of additional pharmaceutical spending. The expansion of its remit has also weakened transparency: public reporting of procurement criteria and pricing is limited, while the overlap with regular reimbursement obscures accountability. The growing leveraging of IFET for routine product distribution reduces pressure on pharmaceutical companies to ensure market availability and continuity of supply through standard channels.

Discussion and Implications

From a rational pharmaceutical policy perspective, the current operational model of IFET generates structural inefficiencies. Its functioning outside the standard pricing and reimbursement framework bypasses the procedural safeguards designed to ensure equitable, evidence-based, and cost-effective access to medicines. To mitigate these distortions, reforms should focus on two strategic dimensions. First, the scope of IFET's mandate should be recalibrated—narrowed to cases of clearly documented supply shortages and clinically justified unmet medical need. Second, IFET-related spending should be fully integrated into consolidated pharmaceutical budget oversight, subject to the same clawback and rebate mechanisms applied to regular reimbursement channels, until these mechanisms are reformed or revamped. These adjustments are essential to restore alignment between IFET's role and its intended mission as a targeted, exception-based procurement instrument within a coherent pharmaceutical governance framework.

The Hellenic Ministry of Health recognizes the importance of reforming IFET's operational model and its overall footprint on the market. A set of recent policy actions by the Ministry of Health signals growing political attention to these challenges. Since July 2024, the newly established EPAS Audit Committee has reviewed requests for non-formulary medicines and issued positive opinions for 14 new active substances or indications, while rejecting 12—an early sign of stricter import criteria based on unmet medical need and demonstrable added clinical benefit (Angelis, 2025). In parallel, IFET has adopted a more assertive buyer strategy, resulting in a 24% reduction in average purchase prices across a wide range of drug codes during the first half of 2024, yielding estimated savings of over €30 million (Angelis, 2025). This approach is supported by the development of a digital platform for the comparison of supplier offers for requested IFET medicine orders. Further, a new electronic interface for the management of emergency imports and order forecasting is being rolled out, aimed at improving coordination with EOF and EOPYY, both of which are urgently needed.

Together, these reforms mark a step toward tighter stewardship, procedural clarity, and strategic alignment. Their consolidation and institutionalisation will be critical to transforming IFET into a fit-for-purpose procurement channel that complements—rather than competing with—the formal reimbursement system in Greece.

References

Hellenic Ministry of Health (Angelis, A)., 2025. Pharmaceutical Expenditure Control: Which measures have been working - Which reforms do we need. Personal communication with the Secretary General for Strategic Planning, October.

Chapman, S., Szklanowska, A., Lopert, R., 2023. Exploring the feasibility of monitoring access to novel medicines: A pilot study in EU Member States (No. No.151), OECD Health Working Papers. OECD Directorate for Employment, Labour and Social Affairs, Health Division, Paris.

EFPIA, 2022. The root cause of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines (PDF). European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium.

European Medicines Agency, 2010. Questions and answers on the compassionate use of medicines in the European Union.

Foundation for Economic & Industrial Research (IOBE), 2025. The Pharmaceutical Market in Greece: Facts & Figures 2024 (PDF). Hellenic Association of Pharmaceutical Companies, Athens.

IFET, 2025a. Institute of Pharmaceutical Research & Technology (IFET) : Profile.

IFET, 2025b. Institute of Pharmaceutical Research & Technology (IFET) : Activities - Pharmaceutical Coverage Unit.

IFET, 2025c. Medicine List.

IFET, 2024. Annual Financial Statement: 2024 (PDF), Annual Financial Statements. Institute of Pharmaceutical Research & Technology (IFET), Athens.

National Medicines Agency (EOF), 2020. Circular - Subject: Coverage of Public Health needs through the process of hospital order of medicines for administration within approved indications.

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