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Policy Briefs on Pharmaceutical Policy Interventions in Greece and their Impact

Mandatory Prescribing Protocols: A Development That Is Long Overdue

Panos Kanavos and Panos Therianos

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LSE Consulting

+44 (0)20 7107 5215
consulting@lse.ac.uk
lse.ac.uk/consultancy

LSE Consulting
Houghton Street
London WC2A 2AE

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Abbreviations

EOPYY	National Organization for the Provision of Health Services
EOF	National Medicines Agency
FEK	Issue of the Official Gazette of the Hellenic Republic
HTA	Health Technology Assessment
IDIKA	Electronic Governance of Social Insurance
KMES	Department of Prescription Processing and Control
MoH	Ministry of Health
OECD	Organisation for Economic Co-operation and Development
PCSK9	Proprotein Convertase Subtilisin/Kexin Type 9

Background

Therapeutic prescribing protocols are essential instruments of a rational pharmaceutical policy framework. Their enforcement ensures that medicines are prescribed according to clinical evidence, therapeutic value, and cost-effectiveness, linking clinical practice to system sustainability. In Greece, although a national e-prescription platform has been in place for more than a decade (Greek Government Gazette, 2010), the development and integration of prescribing protocols has remained inconsistent and lagged behind expectation. Fragmented implementation and weak monitoring have limited the capacity of the digital prescribing infrastructure to drive rational medicine use and expenditure control. The result is a policy gap: a technically capable system consistently under-utilized as a mechanism for promoting rationality and efficiency as well as aligning prescribing behaviour with evidence-based standards.

Objective and Approach

The objective of this brief is threefold: first, to examine the evolution of the development and implementation of therapeutic prescribing protocols in Greece in the period from 2012 to 2024; second, to assess their integration into the e-prescribing system and identify barriers to effective enforcement; and finally, to estimate the impact of imperfect compliance in terms of pharmaceutical expenditure that could have been lower through adherence of prescribing practice to protocol recommendations.

The analysis combines review of the relevant legislation published in the Official Gazette of the Hellenic Republic over the years 2012 to 2024, extraction of data from the e-prescription database of the Electronic Governance of Social Insurance (IDIKA) and secondary analysis of EOPYY prescribing patterns, as captured by the Department of Prescription Processing and Control (KMES).

Legislation Review

The following table summarizes and presents the series of legislation acts that were key in the development and implementation journey of therapeutic prescribing protocols as an element of the national prescribing system in Greece, during the period from 2012 to 2024 (**Table 1**).

Table 1: Overview and evolution of legislation on the development and implementation of therapeutic prescribing protocols in Greece, 2012-2024

Legislation Act	Timing of Introduction	Description of Intervention
FEK B3057	November 2012	Compliance of physicians with the therapeutic protocols of EOF in their prescribing choices made mandatory
FEK B3117	December 2013	Creation of the National Committee for the Monitoring of Pharmaceutical Expenditure and the Implementation of Therapeutic Prescribing Protocols
FEK B1796	July 2014	Minimum target thresholds for the percentage share of generic medicines in the monthly total prescriptions of every prescribing physician prescribing set for the first time Maximum caps imposed on the total value of physicians' monthly prescriptions in terms of reimbursement cost to EOPYY
Law 4316	December 2014	Defined rewards to prescribers for good compliance with minimum generic prescribing targets and maximum prescription cost limits Defined violations of prescription cost limits and associated penalties to prescribers
Law 4472	May 2017	Compliance with therapeutic prescribing protocols in prescribing practice made a necessary requirement for the reimbursement of specific medicines (or groups of medicines)
FEK YODD221	May 2017	Remit of the National Committee amended. Remained in charge of further processing existing therapeutic protocols, developing new protocols and patient registries for chronic diseases. Made responsible for the incorporation of new medicines admitted to the positive list into the existent therapeutic protocols and the sharing of the updated protocol versions with IDIKA for their timely integration in the e-prescription system.
FEK B2141	June 2017	National Committee's size increased to 19 members
Law 4512	January 2018	Required the integration of prescribing protocols into the e-prescription system's digital platform
FEK B828	February 2024	Monitoring indicators introduced on the e-prescription system to improve oversight of prescribers' compliance to protocol guidance and identify breaches (*e.g.*, overprescribing)

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

Results

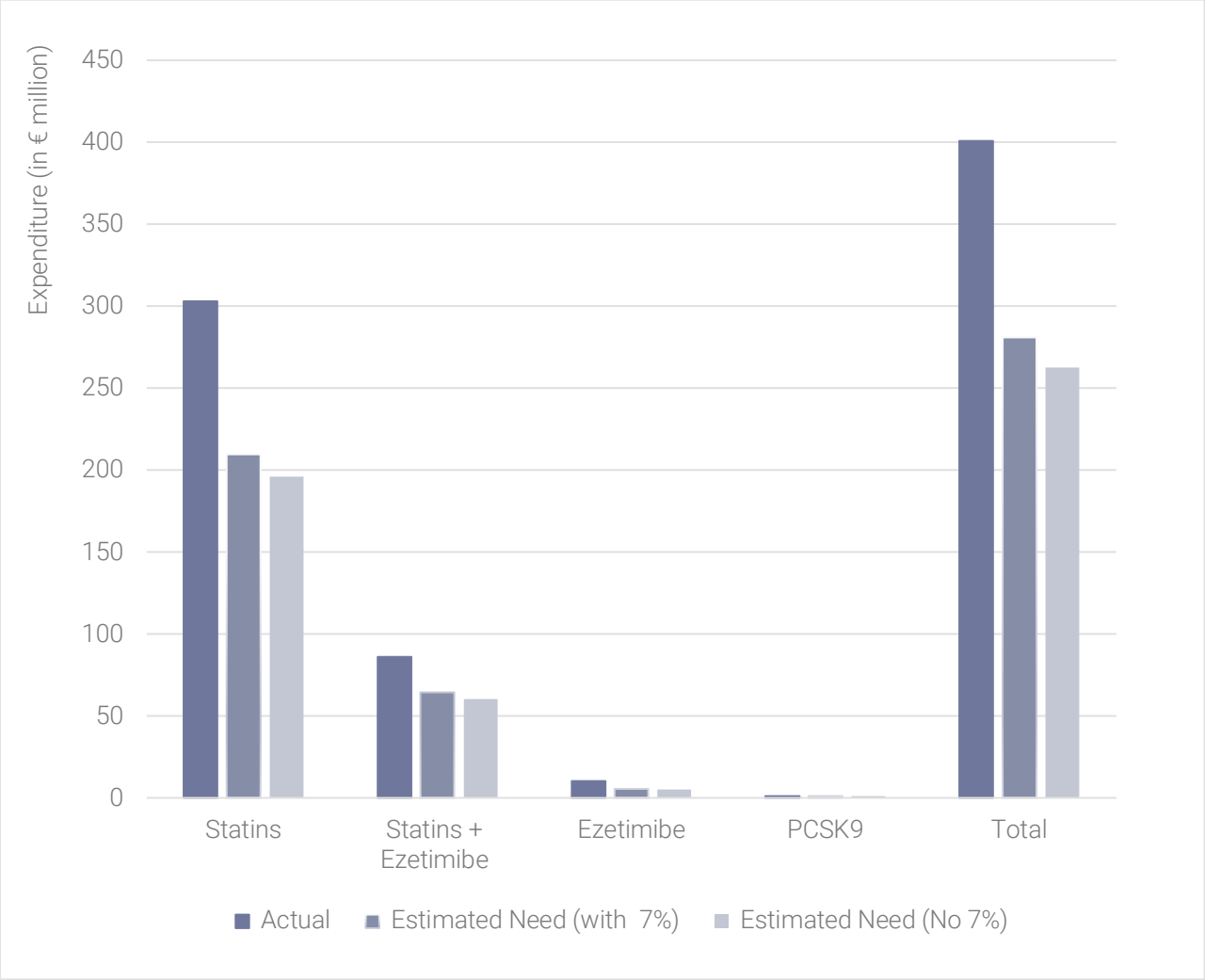
Despite a decade of legislative reform and significant investment in digital infrastructure, the integration of therapeutic prescribing protocols into Greece's e-prescription system remains partial. By 2024, approved protocols by the MoH covered only a limited range of conditions, leaving high-cost therapeutic areas without comprehensive prescribing guidance. Even where protocols exist, they are not fully embedded in the e-prescription platform, allowing

prescriptions outside recommended parameters with few automated restrictions or feedback mechanisms.

The current monitoring and enforcement framework suffers from several weaknesses. Compliance indicators are underdeveloped and designed primarily to identify excess monthly prescription cost compared to prescribers' predetermined targets. However, other violations of established protocol recommendations – such as prescribing a drug at an earlier line of therapy than suggested – rarely trigger review or corrective action, remaining largely undetected. While IDIKA's technical capacity for monitoring prescribing behaviour is considerable, the link between prescribing data and reimbursement oversight is not robust as yet. Additionally, identification of prescribing by indication remains problematic; consequently, it is not feasible to identify for which indication a specific medicine has been prescribed.

Empirical modelling of prescribing for dyslipidaemia illustrates the magnitude of the inefficiency stemming from imperfect observation of the relevant protocol guidance in clinical practice (Cardiovascular Disease Scientific Working Group, 2024). Full adherence to the protocol's therapeutic algorithm could have reduced EOPYY expenditure in drug therapy for this condition by approximately €120 million in 2024 (**Figure 1**). If compliance were coupled with concurrent pricing reform, such as removal of the 7% price reduction cap postulated by the relevant external reference pricing rule, simulation analysis suggests total savings could be in the region of €138 million. These findings underscore the scale of potentially avoidable spending attributable to deviations from recommended prescribing choices and inconsistent protocol enforcement.

Figure 1: Actual vs. estimated spending on selected medicine groups for the treatment of dyslipidaemia based on level of compliance with the treatment algorithm of the therapeutic prescribing protocol on dyslipidaemia, 2024



Source: (EOPYY, 2025), (OECD Data Explorer, 2025), authors' own estimates.

Discussion and Implications

The limited enforcement of therapeutic prescribing protocols represents a missed opportunity to promote rational medicine use in Greece and enact effective demand-side management of pharmaceutical expenditure through volume control, before having to resort to ex-post fiscal instruments such as the clawback in an attempt to contain cost reactively.

To make this shift, protocol compliance must become a binding requirement for reimbursement while enforcement ought to be mandatory and systematically monitored. IDIKA's system should generate real-time alerts, integrate automated audit and feedback functions, and incorporate appropriately-designed indicators capable of detecting deviations

from protocol recommendations beyond just overruns of monthly prescription value ceilings. A further update include the ability to identify drug use (a) based on indication as many (new) drugs are available for multiple indications and (b) based on line of therapy.

At the same time, it is a pressing need for therapeutic prescribing protocols in Greece to be aligned with HTA outcomes, including therapeutic positioning, ensuring that evidence on clinical and cost-effectiveness directly informs prescribing pathways. Regular updates, transparent reporting, and explicit accountability for non-adherence would deliver measurable efficiency gains on this front.

Embedding these reforms within the rational pharmaceutical policy framework would transform protocols from a static reference into a live governance instrument – linking evidence generation to clinical practice, improving efficiency in the use of resources and contributing to the rationalization of pharmaceutical expenditure.

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