

Life Sciences & Healthcare Briefing: Special Edition

Key Reforms Introduced by the New Law Aimed at Modernizing the Public Healthcare System and Healthcare Services

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A. Introduction

1. Law 5243/2025¹ (the **Law**) introduces comprehensive provisions with a view to modernizing Greece's healthcare system, strengthening operational efficiency and ensuring sustainable pharmaceutical spending.
2. It aims to improve the quality, accessibility and flexibility of healthcare services, while aligning national processes with EU standards.
3. This Briefing highlights the most significant changes introduced by the Law in so far as they relate to the pharmaceutical industry.

B. National Health System Healthcare Professionals – Private Sector Practice

1. The Law broadens the categories of healthcare professionals (**HCPs**) working within the National Health System (*Εθνικό Σύστημα Υγείας*) (**NHS**) who can also engage in specific private sector activities. HCPs serving in Local Health Teams (*Τοπικές Ομάδες Υγείας*) and Mental Health Units (*Μονάδες Ψυχικής Υγείας*) are now included in the group of HCPs permitted to work in the

¹ Gov. Gaz. A' 187/31.10.2025 on provisions for the Strengthening of Public Health and the Upgrading of Health Services.

private sector, such as NHS staff, trainee HCPs and assistant HCPs.

2. With the authorization under Law 2889/2001, NHS HCPs may run private practices or provide services to private clinics, laboratories, pharmaceutical, medical device companies and other private healthcare entities.
3. The Law provides an exception allowing assistant NHS HCPs to work in certain activities in the private sector, provided this does not interfere with their NHS duties, pertain to the professional pursuit of commercial activity, or entail participation in private companies.
4. Authorization is granted by the Director or Chairperson of the relevant institution and may be revoked in the same manner².

C. Palliative Care Facilities (Δομές Ανακουφιστικής Φροντίδας)

1. Existing in-patient or home-based palliative care facilities that have been operating for at least 5 years are considered to be operating legally.
2. These facilities may be granted an operating certificate from the competent Regional Authority by 31 December 2031 as an exception to the standard regulatory requirements³.

D. Evaluation Committee (Επιτροπή Αξιολόγησης) – Additional Roles

1. **Joint EU Consultations and Assessments:** The Law broadens the Evaluation Committee's responsibilities⁴:
 - a. The Committee now plays a key role in supporting joint scientific consultations and joint clinical assessments under the EU rules⁵.
 - b. Specifically, it coordinates the participation of experts, co-evaluators, patient representatives and other stakeholders, ensuring that national procedures align with broader EU standards and practices.
2. **National Health Technology Assessments:** Under the new framework, when a national Health Technology Assessment (HTA) overlaps with an EU joint assessment, the Evaluation Committee adopts a structured approach:
 - a. It draws on published EU assessment reports and other relevant EU data, carefully considers the developer's submissions for the national evaluation and avoids requesting information already submitted to the EU.
 - b. The Committee shares the results of the national HTA with the EU coordination team within 30 days.
 - c. This process promotes efficiency, supports evidence-based decision making and ensures

² In line with Law 3329/2005.

³ Set out in Article 13 of Law 5007/2022.

⁴ Amending Law 4512/2018.

⁵ Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health-technology assessment and amending Directive 2011/24/EU, Article 8.

that assessments reflect the specific needs of the Greek healthcare system.

3. **Impartiality and Conflict of Interest Restrictions:** Conflict of interest provisions have been strengthened in line with EU regulations⁶:
 - a. The restrictions are extended from second degree blood relatives to include immediate family members. In this way, Evaluation Committee members and their immediate family are prohibited from holding any direct financial interest in companies that are marketing authorization holders (**MAHs**) or manufacturers or wholesale distributors of medicinal products (the **Companies**).
 - b. This restriction applies for two years prior to their appointment, at the time of their appointment and throughout the duration of their service as Evaluation Committee members.
 - c. Direct financial interest is broadly defined to include:
 - i. employment, consulting or contractual relationships (including independent service providers);
 - ii. the ownership of financial instruments (such as capital, shares, bonds and stock options), royalties and intellectual property rights; or
 - iii. participation on boards of directors or as legal representatives of the Companies.
 - d. Evaluation Committee Members and their immediate family members must not hold any other interests related to the Companies during their service.
 - e. Together, these strengthened provisions reinforce the Evaluation Committee's independence, ensuring that its work remains objective, transparent and aligned with the principles of public trust and high-quality assessment of health technologies.

E. Mandatory Return Mechanism (Clawback)

1. The Law introduces a series of amendments to the clawback mechanism⁷.
2. **Expenditure Limits (2023–2030):** From 2023 to 2030, the expenditure limits for pharmaceutical and healthcare services will be adjusted solely based on the projected annual change in real GDP at constant prices, as reflected in each year's State budget. The Minister of Health may set additional criteria for allocating limits among subcategories within the main pharmaceutical expenditure categories.
3. **Clawback Notes and Adjustments:** Clawback notes will be issued based on the total annual limits for each expenditure category, which include the maximum surcharges specified in the same provision. These surcharges are allocated across expenditure categories pursuant to a joint decision issued by the Ministers of Health, and of National Economy and Finance. Any differences found after final accounting must be reconciled through updated clawback notices

⁶ Article 5 of EU Regulation 2021/2282.

⁷ Under Article 25 of Law 4549/2018.

within the same year. For 2022, any required adjustments will be confirmed in the next application of the clawback mechanism.

4. **Special Adjustment for 2025:** A new paragraph (2B) sets the 2025 healthcare services expenditure limit at €1.698bn. Within this amount, the main category '*E – Diagnostic Tests and Procedures*' is increased by €30m and the main category '*A Private Clinic Hospital Services*' is increased by €5m. These increases are explicitly excluded from forming the basis for expenditure calculations in subsequent years.
5. **Provision for Influenza Vaccines (2024):** Paragraph 7 establishes a special provision for 2024 regarding influenza vaccines. Costs of influenza vaccines purchased by MAHs or pharmaceutical companies that were not distributed or were returned due to lack of demand may be offset in whole or in part against amounts owed under the clawback mechanism. This offset is granted upon request by the MAH or company, in accordance with detailed rules set by a joint ministerial decision which specifies procedures for submission, documentation, cost calculation, refund determination and offsetting and reallocating the financial impact.
6. **Accounting Procedures:** Article 30 of the Law clarifies accounting procedures and reconciliation process for clawback-related settlements⁸. Until now, issued credit invoices were not sufficient for pharmaceutical companies to offset clawback amounts with debit invoices from hospitals. Pharmaceutical companies may now issue debit invoices of equal value to NHS hospitals and the General Hospital of Thessaloniki '*Papageorgiou*'. A credit invoice of equivalent value is subsequently issued to the National Centralized Health Procurement Authority (*EKAPY – ΕΚΑΠΥ*), which allows them to recognize the outstanding clawback amounts as revenue and the respective offset to be made with pharmaceutical companies. Detailed procedures and documentation requirements will be determined by a joint decision of the Ministers of Health, and of National Economy and Finance.
7. **Objective and Impact:** Overall, these changes aim to align the clawback mechanism with current economic conditions, provide flexibility for specific expenditure categories and exceptional cases and enhance transparency, fairness and efficiency in reconciling pharmaceutical and healthcare expenditure between companies, hospitals and public authorities.

F. Inclusion and Assessment of Biomarker Tests

1. The Evaluation and Reimbursement Committee for Medicinal Products for Human Use is now responsible for evaluating companion biomarker tests⁹ alongside the medicinal products they support. The Committee must provide recommendations to the Minister of Health for both the

⁸ Complementing Paragraph 1 of Article 11 of Law 4052/2012.

⁹ Companion biomarker tests are diagnostic tests the results of which determine whether a medicinal product can be prescribed or reimbursed.

medicinal products authorized and marketed in Greece and their associated biomarker tests. This integrated approach ensures that both the medicinal product and its related diagnostic tool are jointly assessed when determining reimbursement inclusion or exclusion from the Positive List.

2. Article 249 of Law 4512/2018¹⁰ has been amended to introduce detailed criteria for the parallel evaluation of biomarker tests and their corresponding medicinal products. Specifically, when the use of medicinal products depends on a biomarker test that is not yet reimbursed by the National Organization for Health Care Services (ΕΟΠΥΥ – ΕΟΠΥΥ), the Committee must evaluate the test at the same time.
3. The assessment considers multiple factors, including:
 - a. analytical validity (sensitivity, specificity, accuracy);
 - b. quality assurance and reproducibility;
 - c. clinical validity and utility;
 - d. test cost;
 - e. inclusion of the test in the cost-effectiveness ratio;
 - f. target population; and
 - g. budget impact.
4. All references to 'medicinal products' in the evaluation procedures now explicitly include biomarker tests.
5. Scientific and academic institutions may access relevant data from the electronic prescription system, subject to data protection rules.
6. Article 250 of Law 4512/2018 has also been updated to formally incorporate biomarker tests into the evaluation process.
7. Overall, these changes establish a comprehensive HTA framework that jointly evaluates medicinal products and their accompanying diagnostic tests, aligning Greece with current EU precision medicine practices. This approach strengthens evidence based and patient centered decision making.

G. Extension of Deadline for Source of Funds Declarations (Πρόθεν Έσχες)

1. The Law extends the deadline for submitting the annual Source of Funds Declarations¹¹ for 2025 relating to the 2024 tax year, postponing the final submission date to 15 November 2025.

¹⁰ Gov. Gaz. A' 5/17.01.2018 on Regulations for the implementation of the Structural Reforms of the Economic Adjustment Program and other provisions.

¹¹ Established under Articles 18 and 23 of Law 5026/2023 [Gov. Gaz. A' 45/28.02.2023 on the Submission of source of funds declarations (πρόθεν έσχες) and financial interests – Provisions to strengthen the European Public Prosecutor's Office – Other urgent provisions].

H. Summary

1. This Law represents an important step forward in modernizing Greece's healthcare framework. It strengthens the professional landscape for NHS HCPs, supports the development of palliative care services and ensures Greece's alignment with EU standards in HTA. The reinforcement of conflict of interest rules enhances transparency and public trust, while the integration of biomarker tests in reimbursement evaluations marks a pivotal shift toward personalized and evidence based healthcare.
2. The updated clawback provisions aim to resolve practical issues arising from the transition to EKAPY's central procurement management.
3. Collectively, these reforms reflect a strong commitment to building a resilient, transparent and innovation-driven healthcare system that addresses both economic and clinical challenges, ensuring sustainable access to high-quality care for all.



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