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Law 5302/2026 for the Establishment of an Innovation Fund, Patient Access to New Medicines and Treatments, Improvement of Health Services and Other Provisions

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Law 5302/2026 for the Establishment of an Innovation Fund, Patient Access to New Medicines and Treatments, Improvement of Health Services and Other Provisions

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On May 15, 2026, Law 5302/2026 (Government Gazette A' 78/20.05.2026) entitled "Establishment of an Innovation Fund – Patient Access to New Medicines and Therapies – Improvement of Health Services and Other Provisions" (hereinafter referred to as the "Law") was adopted.

Background

The Law introduces a broad set of reforms aiming to improve patients' access to innovative medicinal products and therapies, strengthen the operational framework of the National Organization for Health Care Services ("EOPYY"), ensure adequate market coverage and enhance transparency in the distribution and reimbursement system. It further includes provisions concerning the protection of minors from tobacco and cannabis products, as well as measures to upgrade the overall quality and efficiency of the national healthcare system.

The key provisions of the Law are summarized as follows:

Chapter A: Establishment of an Innovation Fund and Procedure for the Inclusion of Innovative Medicines

An Innovation Fund is established within EOPYY as a **separate category of pharmaceutical expenditure, intended to ensure patient access to** medicinal products that have received a marketing authorization by the European Medicines Agency ("EMA") and are classified as **Advanced Therapy Medicinal Products ("ATMPs") and/or Priority Medicines ("PRIME").** The Innovation Fund is financed through state resources and is monitored separately by EOPYY.

Medicinal products are eligible for inclusion in the Innovation Fund subject to the cumulative conditions set out in Article 4 of the Law, namely: (i) inclusion of the product in the annual report submitted by the marketing authorization holder (MAH) to the Horizon Scanning service of Article 10 of Law 4931/2022, (ii) submission of a request by a scientific company, recognized by the Central Board of Health, to the Innovation Fund Committee regarding the necessity of the treatment for a specific patient, (iii) commitment of the MAH to provide the product for the full duration of the patient's treatment, and (iv) conclusion of an agreement between the MAH and the Innovation Fund Committee.

A **nine-member Innovation Fund Committee** is established within the Ministry of Health, competent for reviewing applications for inclusion of innovative medicines in the Innovation Fund, issuing relevant opinions to the Minister of Health, and concluding agreements with MAHs regarding the entry, stay and withdrawal of medicines from the Innovation Fund.

Under the prescribed procedure of Article 6 of the Law, where a product has not already been priced, prior to the submission of application for inclusion in the Innovation Fund, MAHs must

request EOF to determine a provisional price for such product. Following submission of the MAH's application to the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use, and the Committee's subsequent opinion that the product cannot be immediately recommended for reimbursement, the MAH may request its inclusion in the Innovation Fund. **During its inclusion in the Innovation Fund, the product is exempt from clawback obligations,** subject to limited exceptions provided by the Law.

Upon withdrawal from the Innovation Fund, a **negotiation procedure for the determination of the reimbursement terms of the product with the Negotiation Committee is established**; failure to conclude an agreement with the Negotiation Committee results in exclusion of the product from the positive list of Article 12 of Law 3816/2010. Where the product is deemed necessary by the treating physician for the continuation of the patient's treatment, the MAH must provide the product **free of charge** in cases where: (i) the treatment lasts up to three (3) months, or (ii) the treatment is chronic and no significant additional clinical benefit has been demonstrated. Where significant clinical benefit is demonstrated, the MAH shall provide the product under the financial terms applicable during the product's inclusion in the Innovation Fund.

Finally, the **National Registry of Innovation Fund Patients** is established within the Ministry of Health to record patients receiving treatments included in the Innovation Fund.

For the effective implementation of the procedural aspects governing the operation of the Innovation Fund, further guidance and clarification is anticipated to be provided through the issuance of the relevant Ministerial Decisions referred to in Article 89 of the Law.

Chapter B: Provisions for Pharmaceutical Expenditure and EOPYY

Under Article 8 of the Law, the possibility for the **development, training and use of AI systems to support the operation and decision-making process of EOPYY,** strictly within the scope and for the purposes set out under said Article, is introduced.

Additionally, the Law further **expands the pharmaceutical clawback scheme to include, as of January 1, 2026, the hospitals of the Ministry of National Defense and the Army Equity Fund Hospital ("NIMTS")**. The National Centralized Health Procurement Authority ("EKAPY") undertakes the procedure of calculating clawback amounts, per pharmaceutical company or per MAH, for the total pharmaceutical expenditure of these entities.

In addition, Article 12 of the Law substantially amends the **categories of medicinal products falling within the scope of the Electronic Pre-Approval System of EOPYY**. In particular, the Law extends the framework currently applicable to high-cost medicines and early access medicines granted temporary individual authorization by EOF, to include the following categories: **(i) medicinal products,** whether marketed or not, **which are not reimbursed in Greece for approved indications, provided that such products are reimbursed for a specific therapeutic indication in at least five (5) of the following EU Member States,** maintaining a health technology assessment mechanism, namely Belgium, France, Denmark, Spain, the Netherlands, Poland, Portugal, Slovenia, Sweden, Czech Republic and Finland, **and are supplied through emergency imports or individual requests.** In the case of orphan medicines, reimbursement in at least four (4) of the above Member States is required; **(ii) medicinal products included in the positive reimbursement list for the treatment of non-reimbursed, (non-) approved indications,** which are **requested exceptionally in cases of life-**

threatening diseases, or conditions capable of causing irreparable harm; and **(iii) medicinal products,** whether marketed or not, **which are not reimbursed in Greece and are intended for administration of non-approved indications concerning diseases with documented geographical concentration or increased incidence in the Greek population, life-threatening or severely debilitating pediatric diseases, or extremely rare orphan diseases.** The Law also allows the submission of a reasoned application to the Electronic Pre-Approval System, under exceptional circumstances requiring the urgent administration of a specific product, even when the statutory criteria are not fully met. It should be noted that, pursuant to Article 90 of the Law, the provisions of Article 12, as well as Article 15 concerning the procedure for submitting and examining applications to the Electronic Pre-Approval System of the Law do not apply to treatments already initiated prior to the Law's entry into force.

Furthermore, the composition of the competent Audit Committee of the Electronic Pre-Approval System of EOPYY is amended, while the incompatibilities applicable to the consulting physicians of the Electronic Pre-Approval System are aligned with those governing the Audit Committee of the Electronic Pre-Approval System, instead of those of the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use, as was provided under the previous framework.

Finally, from **December 1, 2025, the Ministry of National Defense and NIMTS are included within the scope of the Medicinal Product Price Negotiation Committee**, while from July 1, 2026, EKAPY assumes responsibility for the procurement procedures of all medicinal products for those entities.

Chapter C: Provisions for the National Organization for Medicines ("EOF") and Pharmaceutical Warehouses

The Law introduces **Article 8A to Legislative Degree 96/1973, concerning the prioritization of stocks of emergency-imported medicinal products in cases of suspension of distribution or shortage of supply.**

Specifically, where a MAH declares the suspension of distribution or shortage of a medicinal product for a specific period of time but subsequently does not suspend the product's distribution or resumes its distribution within the declared period, emergency-imported products, including original and generics, shall be distributed on a priority basis until stock exhaustion. In the event of a repeated declaration of suspension of distribution or shortage within the same year, administrative fines may be imposed.

The Law further **prohibits the wholesale distribution and purchase of medicinal products by pharmacies or entities lacking a wholesale distribution authorization**, where such activities are carried out **for the purpose of stockpiling or collecting such products for export**, and establishes the applicable sanctions in the event of a breach.

Chapter D: Provisions for the Distribution and Sale of Medicinal Products and Private Pharmacies

The Law permits the **free distribution of medicinal products**, original and generics, which are **imported on an emergency basis by the Institute of Pharmaceutical Research & Technology S.A. ("IFET S.A.") and are classified as 'slow-moving',** for a period of more than one (1) year, upon a relevant decision of IFET's Board of Directors.

Additionally, the Law regulates **the non-routine production and administration procedure of ATMPs, which are produced for specific patients upon the treating physician's request**

and administered in public or private hospital facilities in Greece under the treating physician's exclusive responsibility. Sanctions in cases of breach of the relevant authorization, production, administration, pricing and reimbursement procedures, as well as pharmacovigilance requirements applicable for ATMPs, as determined by a joint decision of the Ministers of Health and National Economy and Finance, are furthermore introduced.

Chapter E: Provisions for Tobacco Products, Medicinal Cannabis and Cannabis Products

The Law imposes **stricter administrative penalties for violations of the terms of sale, offer and distribution of tobacco, nicotine and alcohol products to minors**, while also amending separate provisions of Law 5216/2025 governing electrically heated smoke-free and nicotine products, for the protection of minors.

In parallel, the Law introduces **a nationwide prohibition of the retail sale, distribution, supply, purchase and use by consumers of dried cannabis flowers derived from the cultivation of cannabis varieties of the Cannabis Sativa L. species with a tetrahydrocannabinol (THC) content of up to 0.3%, whether raw or processed**. The prohibition does not, however, extend to the import, storage, wholesale supply and distribution of dried flowers intended exclusively for industrial processing.

The Law further establishes the **licensing, operation and supervision framework for cannabis product trading businesses,** as defined within the Law, and creates a **Digital Cannabis Product Control Registry.** Existing cannabis product trading businesses are required to comply with the provisions of Chapter E of the Law within six (6) months from its entry into force.

Chapter F: Provisions for the Central Service of the Ministry of Health and its Supervised Bodies, Hospitals of the National Health System and Private Clinics

The Law establishes the **framework for Joint Procurement (J.P.) agreements for medicinal products, vaccines and medical devices among EU Member States**, which is overseen by the General Secretariat for Strategic Planning of the Ministry of Health, assisted by the Secretary General for Public Health, through the EU Health Emergency Preparedness and Response Authority ("H.E.R.A."). The import of the above products and conclusion of relevant agreements are carried out by IFET S.A..

Chapter G: Provisions for Doctors, Hospital and Healthcare Facilities Staff

The Law abolishes possibility for family doctors contracted with EOPYY to conduct home visits.

The current framework establishes the **governance system of the National Telemedicine Network ("EDIT")**, developed under the framework of the National Recovery and Resilience Plan "Greece 2.0", aiming to expand remote healthcare services, interconnect national public health structures and improve the accessibility and efficiency of the National Health System.

Lastly, the Law provides for the creation of a dedicated **electronic application for oncology and hematology patients, enabling graded access to patient health data** related to the diagnosis, monitoring and treatment of patients with relevant diseases.

Other Provisions

The Law also includes various additional and emergency provisions relating to, among other things, the operation of AI applications in the Personal Electronic Health Record, the extension of certain provisions addressing the COVID-19 pandemic, as well as the obligations applicable to veterinarians and livestock farm owners.

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