Administrative Law Briefing: Special Edition

Council of State Ruling on EOPYY Claw Backs for Medical Devices, Consumable Healthcare Materials and Special Nutrition Supplements

A. **The Court's Key Findings**
B. **Detailed Rulings**

The Sixth Chamber of the Greek Council of State (**CoS**), in a seven member composition, has delivered a series of rulings on multiple petitions for annulment challenging the claw back mechanism imposed on manufacturers, importers, suppliers and distributors of medical devices, consumable healthcare materials and special nutrition supplements under the EOPYY reimbursement system.

This Briefing summarizes the new case law regarding the challenges of claw backs for 2017 and 2018 that have already been contested within the relevant deadlines.

A. The Court's Key Findings

Period	Ruling	Key Takeaways
2017	The Court annulled the claw back, finding that the EKAPY–EOPYY Registry system was inadequately regulated and that the statutory preconditions for imposing the measure had not been met.	Market participants who have already challenged 2017 claw back assessments within the relevant deadlines may benefit from a strong basis for annulment where products had not been properly brought into the EOPYY reimbursement Registry regime and pricing used retail rather than import/wholesale prices.
2018	The Court upheld the claw back, holding that parties who registered products in the Registry during that year accepted the transactional framework and the business risk; the measure was neither	Those assessed for 2018 face a significantly higher threshold for constitutional challenge, but the minority opinion preserves arguments in existing

	disproportionate nor unforeseeable at the material time. A significant **minority** of the bench dissented, concluding that the relevant provisions violated the principles of legal certainty, foreseeability and proportionality, and should therefore be annulled as contrary to supra-legislative principles.	proceedings. Market participants should continue compliance and budgeting for uncapped claw back overruns. Foreseeability and constitutional challenges are unlikely to succeed in light of the majority's reasoning and the Plenary's earlier endorsement[1].

B. Detailed Rulings

Detailed Ruling on the 2017 Claw Backs

The central question was whether the claw back on EOPYY expenditure for medical devices, consumable healthcare materials and special nutrition supplements could lawfully be imposed on importers for the disputed 2017 year[2].

The Court held that:

1. The claw back presupposes that the relevant products are included in EOPYY's reimbursement system via their registration in the EKAPY–EOPYY Registry upon application by the obligated parties.
2. The Registry registration system was not adequately regulated during 2017.
3. Importers who were not contracting parties with EOPYY did not, by law, have negotiating power by virtue of that status and could not contribute, even indirectly, to setting maximum reimbursement prices based on the declared external reference price.
4. As a consequence, the reimbursement prices used for calculating the claw back coincided with retail prices and were far removed from import/wholesale prices.
5. Applying the supra-legislative principle of legal certainty, the Court concluded that Laws 4447/2016 and 4461/2017 could not apply for the disputed 2017 year.
6. On that basis, the application for annulment was upheld and the acts imposing claw backs for the first and second quarters of 2017 were annulled in their entirety.

Detailed Ruling on the 2018 Claw Backs

[1] CoS 904–905/2024.

[2] The first period of the new regime under Article 100 of Law 4172/2013 (as amended by Article 34(1) of Law 4447/2016).

The question before the Court was whether the measure which limits the revenues derived from an indirect relationship with EOPYY is constitutional and proportionate.

1. The majority held that the claw back is imposed not on providers contracted with EOPYY as a cap on their claims, but on manufacturers (domestic products) or importers, suppliers or distributors (for products from other countries) who effected the relevant registration.
2. By registering products in EOPYY's Registry of Reimbursable Products upon their application, as announced and essentially operating in 2018, those parties accepted the relevant transactional framework and the associated business risk.
3. The Court found that the measure aimed at reducing EOPYY expenditure and safeguarding the public health system given fiscal conditions[3], does not violate Article 5(1) of the Constitution and is not disproportionate as it does not affect the entirety of business activity. Those addressed were assessed by the legislature to have economic and negotiating power to shape selling prices.
4. The measure is accordingly neither unsuitable nor unnecessary, even though the full overrun is allocated to them without a cap.
5. The consequences of the measure were sufficiently foreseeable at the material time, and no special impact study was required before setting annual or semi-annual EOPYY spending caps.
6. The application for annulment was dismissed. A minority of the bench dissented, holding that Article 34 of Law 4447/2016 radically altered the EOPYY insurance regime for the products at issue and that the change was not reasonably foreseeable. While containing public expenditure and ensuring system viability can justify restrictions to economic freedom, this presupposes adherence to equality, proportionality, non-infringement of core rights and rule-of-law principles including clarity and foreseeability. The minority found those principles were not met because:

    a. the measure was introduced abruptly in December 2016 without evidence of prior planning and without reasons in the explanatory memorandum for burdening manufacturers, importers and distributors;

    b. later legislature[4] shifted the burden solely to contracted providers, referring to a 'restoration of the order of things', implicitly acknowledging the prior regime was irregular; and

    c. the provisions were ambiguous even as to addressees, creating a fluid, constantly changing environment lacking foreseeability and clarity.

    In the minority's view, the contested acts should be annulled as based on provisions contrary to

[3] see Plenary CoS 904–905/2024.
[4] Article 4 of Law 4931/2022.

principles of supra-legislative force.



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