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Greek Council of State upholds constitutionality of clawback post COVID-19

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On June 19, 2024, the Plenary Session of the Greek Council of State issued two significant decisions (No. 904 and 905/2024). These rulings upheld the constitutionality of a measure requiring holders of marketing authorizations for medicinal products to retroactively reimburse EOPYY for outpatient pharmaceutical expenses that exceeded the annual budget. This measure, initially established by article 11 of Law No. 4052/2012 for the period 2012-2015, was extended to cover the period 2015-2018, and further extended to 2019-2022 by Article 25 of Law No. 4549/2018.

The rulings stated that the legislative measure introduced by laws 4052/2012 and 4549/2018 legitimately restricts the constitutionally protected freedom of access to and development of productive and commercial activities. This is because the measure aims to serve a public interest: aligning pharmaceutical expenditures with the average of EU member states and ensuring universal pharmaceutical coverage in a fiscally neutral manner. Therefore, the State has the authority to set the level of public expenditure and the conditions for transactions using general, predictable, and objective criteria, even during crisis conditions and as conditions improve.

According to these rulings, a special study is not required before setting the annual closed budget for pharmaceutical expenditure, as such a study is unnecessary for measures related to the budgetary cost of the supply of goods. It was also

ruled that the clawback measure does not violate the principle of proportionality, as no other specific measures to contain pharmaceutical expenditure were available and not implemented.

Finally, the decisions concluded that the clawback does not violate the principle of equality between undertakings producing generic medicines and those producing original medicines, as these are different entities with different cost structures.

As a result of these rulings, any pending petitions that do not involve claims for orphan drugs are likely to be rejected. However, petitions for annulment and actions concerning clawbacks on orphan drugs or issues not yet decided (such as errors in specific calculations or deficiencies in Ministerial Decisions, that their legality might have not been ruled by the Court until now) remain valid, even if they pertain to the years up to and including 2022.

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