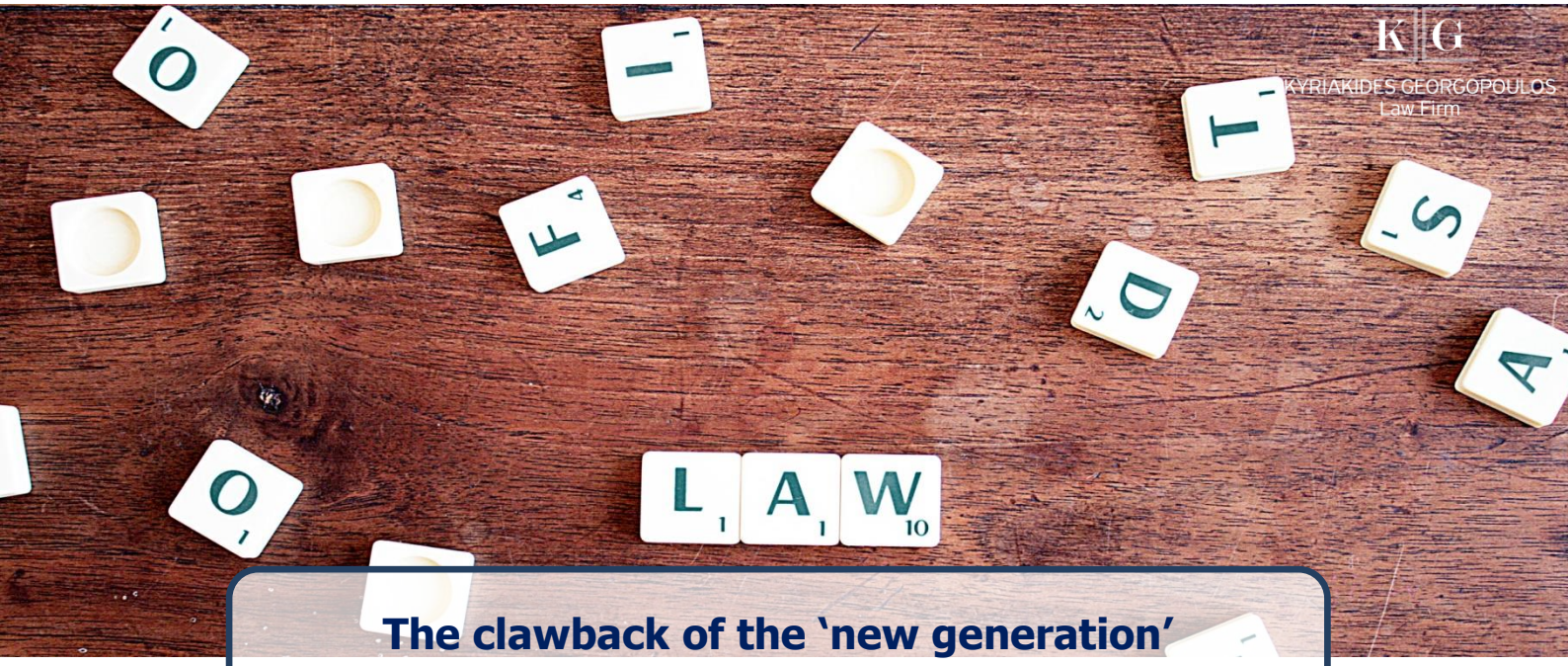

The clawback of the 'new generation' Growth Share criterion and case law

General

The clawback mechanism has been initially established as an emergency measure but as indicated by the Greek case law, it is here to stay:

The Council of the State rules on the Clawback mechanism

More specifically, the claw back mechanism was originally introduced by Article 11 of Law 4052/2012 as a measure to reduce public outpatient pharmaceutical expenditure by 31.12.2015. Further, through the amending and completing of Article 11 of Law 4052/2012 under the provisions of Laws 4346/2015 and 4354/2015 referred to in paragraph 4, the measure was extended to reduce total public pharmaceutical expenditure (out-of-hospital and non- hospital) until 31.12.2018. The measure was introduced as part of the general effort to reduce the public debt and to support the exit of the national economy from the crisis (Decisions of the Council of the State no. 668/2012, 1116/2014). As regards to the need of extension of the measure to hospital pharmaceutical expenditure, the explanatory report ("αιτιολογική έκθεση") of Law 4346/2015 states that:

"Following the introduction of the clawback system to the outpatient pharmaceutical expenditure in 2013, pharmaceutical expenditure made by hospitals, in relation to the costs of pharmaceutical products provided by EOPYY, shows upward trend. Thus, it is evident that all recent successive reductions in drug purchase thresholds in hospital budgets have not led to cost containment. Hence, it becomes clear that there is a need to extend this mechanism to all other public spending on pharmaceuticals, so that all public expenditure on medicines is covered by the system of automatic over-reimbursement (clawback).

The introduction of the system of clawback for all medicines and vaccines purchased by public health institutions, i.e. public hospitals, EOPYY and other healthcare providers, while identifying an adequate spending limit, will enable operators, and especially hospitals, to obtain the necessary pharmaceutical products while ensuring the macroeconomic stability of their budgets. "

Based on the above, the Supreme Administrative Court has further ruled that:

"In order to serve the public interest, and in particular to deal with the acute economic crisis of the country, threatening the collapse of the national economy, the limitation of public expenditure, with a corresponding reduction in the economic demands of individuals, is permissible under the Constitution. The limitation of the pecuniary claims of individuals imposed under the above conditions is not incompatible with the Constitution and Article 1 of the ECHR of the ECHR if the principle of a fair balance between the general interest affecting society and claims for the protection of the fundamental rights of the individual [cf. in relation to Article 1 of the ECHR ECHR, ECHR ..... v. the United Kingdom, judgment of 21.2.1986, which has been consistently followed]. The clawback mechanism of Article 11 of Law 4052/2012, as in force, subject to the marginal control of the Council of State in the circumstances of its adoption, cannot be described as a measure unnecessary and inappropriate. The above reasoning is based to the facts that (A) The measure is temporary and capable of reducing the pharmaceutical expenditure, given that it is sufficient to assess the strength of the national economy during the three years 2015-2018, since it supports the prevention of deliveries of medicinal products which do not meet real therapeutic needs. (B) Before the measure's implementation, it is not possible for a Judge to judge its severity with a view to jeopardizing the core of the rights of pharmaceutical companies, given that the measure presupposes that there will be exceedances of the budgeted expenditure over the three-year period 2015-2018, which are impossible to be estimated in advance (their existence and height).

The evolution: Addition of the Growth Share Criterion

As a result of the above Court's "legalization" of the clawback mechanism and on the authorization of L. 4055/2012, the Ministerial Decision no. οικ. Γ563587/20.08.2015 was issued. The above mentioned decision states that the budget of EOPYY's pharmaceutical expenditure for the year 2017 should not exceed the amount of EUR 1,945 billion, including VAT.

Therefore, the aforementioned Decision no. C563587 / 20.08.2015 of the Minister of Health, was amended by the decision no. C5 (a) / OIK.50389 / 30.06.2017 of the same body, which established two criteria according to which the pharmaceutical companies would be allocated the excess of the pharmaceutical expense. The first criterion is the 90% of the pharmaceutical company market share in the total compensation markets of EOPYY. The second criterion concerns the contribution of each company to the increase in pharmaceutical expenditure (by 10%). Each company is forced to contribute to overpaying pharmaceutical spending when its sales for this year are higher than the previous one and when it introduces new drugs to the EOPYY's compensation scheme.

The exclusion of the Growth Share criterion as regards to the vaccines and generic products

Following the aforementioned no. C563587 / 20.08.2015 Decision of the Minister of Health, as amended, a new Decision Δ3 (a) / οικ. 63585 / 23.08.2018 of the same Minister was issued, expressly excluding the vaccines included in the National Vaccine Program and the generics (during the first two years of their inclusion in the positive list of prescription drugs), from the method of calculation of the overpayment of pharmaceutical expenditure, based on a 10% share of the growth share of each company or CIS, thus returning to vaccines and generics as the basis for calculation only the criterion of the final market shares of each company in the 100%.

An assessment regarding the new criterion (and the present case law)

According to our previous experience and taking into consideration that a) there is no prior adverse case law on the application of the growth share criterion issue, b) the economic crisis –"public interest" reason- that constituted the ratio for the clawback imposition has ended (according to the Prime Minister's relevant declarations), c) the clawback imposition should no longer be considered as an urgent and temporary measure, since it has been extended until 2022 and d) serious law infringements are deemed to be taking place by its imposition, as indicated by the explicit exclusion of the vaccines, and generic products from the implementation of the growth share criterion, the grounds of the previous case law legalization of the clawback mechanism are now alleviated.

Hence, as concluded from the above, the case law regarding claw back mechanisms may be now closer to either major change on its calculation method or to its abolishment as a consequence of a potential positive decision of the Council of the State.

Contact

For any further comment or query, please contact the KG lawyer you are in contact with, the Public/Administrative Law or the Pharmaceutical Law practice team.

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