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## The Council of State annuls a clawback imposition for first time: “The Orphans case”

BY PUBLIC, ADMINISTRATIVE LAW TEAM & LIFE SCIENCES TEAM |  
NOVEMBER, 2019

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By virtue of a recent pioneer decision (1785/2019), the Council of State annulled the imposition of the clawback mechanism on “orphan drugs” on the basis that the imposition of said measure on this particular category of pharmaceutical products and therefore, their equation with other pharmaceutical products, is against the constitutional principles of Equality and Proportionality. In particular, the Court, taking into account that both the number of patients in need of orphan drugs and the cost of their treatment are known in advance and specific, given that the drugs for said specific diseases as well as the calculation of their price are determined strictly by a Ministerial Decision and not according to the market trends, acknowledged that burdening the cost of orphan drugs with clawback inevitably results to unequal and discriminatory treatment to the detriment of pharmaceutical companies marketing “orphan drugs”.

Following the aforementioned reasoning and in light of the indisputable particularities of this special category of pharmaceutical products which are intended for treating people with rare diseases, the number of which remains almost the same every year, the Court accepted that the results of the imposition of the clawback measure to “orphan drugs” is disproportionate to the purpose for which it was initially introduced. In this context, the Court concluded that the burdensome consequences emanating from the imposition of the clawback mechanism to “orphan drugs” do not provide any incentives to pharmaceutical companies so as to encourage the marketing of said products in Greece, which is contrary to the intentions of the European legislator, as stipulated in art 9 par. 1 of the Regulation (EC) No 141/2000.

It is worth mentioning that it is the first time, since the establishment of the clawback mechanism as an “urgent measure of public interest” after the outbreak of the economic crisis in Greece, that the Supreme Administrative Court admits that this extra burden imposed on this category of pharmaceutical products as a result of the clawback mechanism, is against constitutional

principles and therefore, it should be considered as being inappropriate for the objective pursued and as such unenforceable. It goes without saying that this is a landmark decision on the matter at hand, even if it concerns solely a specific category of pharmaceutical products. However, it remains to be seen whether the abovementioned decision will establish new precedents that may affect future judgments related to the new-pending clawback imposition acts on orphan drugs that could be challenged before the Courts.

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