



Payback Decree

Payback on medical devices

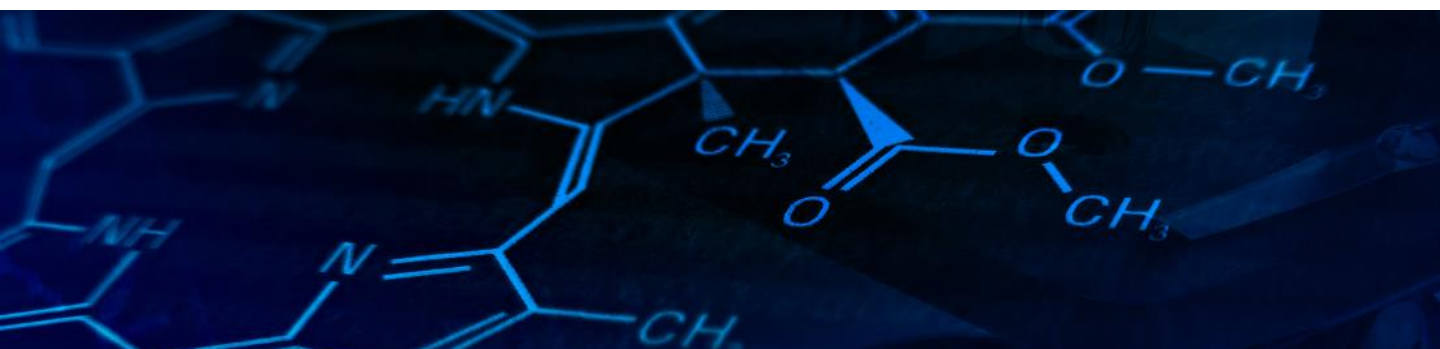
On September 15, 2022, the Decree of the Minister of Health and the Ministry of Economy and Finance (“DM”) has been published in the Official Italian Journal certifying the exceeding of the medical device spending ceiling of **4,4 %** of the National Health Fund for the years 2015, 2016, 2017 and 2018.

Now, it is expected the adoption of a further decree, by the Ministry of Health, in which the procedural modalities for the replenishment and relative guidelines will be defined. **On September 28, 2022, the State-Regions Conference expressed a favorable opinion on the framework of this Decree.**

In particular, with regard to the repayment of the possible regional expenditure overrun for the years 2015, 2016, 2017, 2018, the Law Decree “Aiuti bis” (converted into Law no. 142/2022) provides for a complex procedure that will end with the adoption of a series of measures by the Regions and Autonomous Provinces by which the Companies will be concretely required **to pay an amount that is proportional to the overrun of previously certified expenses**. Specifically, this share is 40% for the year 2015, 45% for the year 2016 and 50% from the year 2017 forward.

The medical devices sector companies will be required to fulfill the payment obligations arising from this provision in favor of Regions and Autonomous Provinces. The local Authorities **have the option of offsetting the debts for purchases of medical devices should the companies fail to comply with the payment.**

Alternatively, **within sixty days** from the adoption of the measure requiring the payment, companies may file to the competent Regional Administrative Court the request for its annulment with suspension.



It is not excluded that **trade associations also intend to challenge the preliminary acts** such as the forthcoming Ministerial Decree, containing the Guidelines and procedural modalities for the payback, as well as the original DM (that certified the overruns, published in the Official Gazette on September 15), should they identify immediate harm, such as the inaccuracy of the calculation basis, the absence of an adequate contradictory discussion up to the very constitutionality of the measure, as occurred for the pharmaceutical payback.

It is therefore important for industry players to **promptly assess** any profiles of immediate harmfulness of the DM in order to consider the advisability of **challenging it within the tight deadline on November 14, 2022**. This is also in order to avoid incurring subsequent declarations of inadmissibility for failure to challenge preliminary acts.

The risk of possible administrative litigation is well known to the Institutions which, during the State-Regions Conference held on September 28, undertook to open a round table with the Ministry of Economy and Finance to *“define common criteria for risk assessment and for the handling of possible litigation”*.

In light of the current scenario, **it is urgent for operators in the medical device sector to have a clear picture of the amounts falling under the payback for the years 2015-2018**.

Deloitte Legal, through a **multidisciplinary team** including tax professionals, could support - in addition to the judicial assistance in the appeal against the Decree - in the reconstruction of the amounts of repayment obligation, as well as in the analysis of the tax implications (both for direct and indirect taxes, for the amounts due and any provisions already made or to be made in the financial statements).

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