

“PAYBACK” OBLIGATIONS IN THE MEDICAL DEVICES’ FIELD

On 15 September 2022, Ministerial Decree No. 216 of 6 July 2022 was published in the Italian Official Journal concerning the *“Certification of the medical devices’ spending exceeding ceiling at national and regional level for the years 2015, 2016, 2017 and 2018”*, bringing to the forefront an issue that had remained dormant until then.

The issue starts from Law No. 111 of 15 July 2011 converting Decree-Law No. 98 of 6 July 2011 - *“Urgent measures for financial stabilisation”*. Article 17, on the subject of rationalization of health budget, introduced the principle according to which expenditure on medical devices, incurred by the National Health Service, should be set within certain ceilings to be defined by subsequent inter-ministerial decrees. Such ceiling was originally set at 5.2% of the ordinary health fund. Furthermore, any repayments were to be borne by the Regions that had contributed to the exceeding.

These ceilings were then progressively reduced: firstly, Decree-Law No. 95 of 6 July 2012 reduced them to 4.9% in 2013 and 4.8% in 2014; then the Budget Law of 2013 reduced them to 4.8% for 2013 and 4.4% for 2014. The latter ceiling is still in force today.

Decree-Law No. 78 of 19 June 2015 (*“Urgent measures concerning local and regional authorities”*, converted into Law No. 125 of 6 August 2015) introduced the provision of imposing on the supplying companies the obligation to pay a portion of any excess of the ceiling by forcing supplying companies to share 40% of such excess for 2015, 45% for 2016 and 50% for 2017.

Moreover, Article 9 *ter* of the aforementioned Decree-Law established that the Ministry of Health, in agreement with the Ministry of the Economy and Finance, would have certified – by 30 September of each year, on a provisional basis, and then by 30 September of the following year, on a definitive basis – the excess expenditure over the regional budget.

However, this mechanism was never implemented. On the contrary, with the Budget Law of 2019, the described procedure was modified: Article 1, paragraph 557, establishes that the Ministry of Health, in agreement with the Ministry of the Economy and Finance, is required to adopt, by 30 September of each year, a Decree certifying the excess over the expenditure ceiling recorded on the basis of the revenue of each company (gross of VAT) according to the data resulting from invoices. This certification should have been made by 31 July 2020 regarding the excess over the expenditure ceiling for 2019 and, for subsequent years, by 30 April of each year.

Even this mechanism was never implemented, thus making the payback a dead letter for almost five years.

In November 2019 two agreements were made in the State/Regions Conference which defined, retroactively, the expenditure ceilings for the years 2015-2018 (7 November 2019 no. 181), as well as the expenditure ceiling for 2019 (7 November 2019 no. 182), postponing the completion of the procedure to measures of the Ministry of Health / Agreement at the State-Regions Conference that must (i) certify the excess of the medical device expenditure ceiling at the national and regional level

from 2015 to 2019 and (ii) establish the procedure of the repayment from 2015 to 2019.

However, it was only with the Ministerial Decree of 6 July 2022, published on 15 September 2022, that the expenditure ceiling for medical devices at national and regional level was certified to have been exceeded, and thus the payback procedure started.

Following the aforementioned Ministerial Decree, suppliers will have to reimburse the National Health Service: Euro 416,274,918 for the year 2015; Euro 473,793,126 for the year 2016; Euro 552,550,000 for the year 2017 and Euro 643,322,535 for the year 2018.

In addition to this, Law No. 142 of 21 September 2022 ("*Decreto Aiuti bis*") provides for (i) the obligation for every Region to publish the list of supplying companies subjected to the repayment for each year within 90 days from 15 September 2022 and (ii) a mechanism whereby the Regions, in the absence of repayment by the supplying companies within 30 days from the publication of the list, may offset their own possible debts against the said repayments.

Lastly, by Decree 6 October 2022, published in the Italian Official Journal No. 251 of 26 October 2022, the preliminary guidelines were adopted for the issuance of regional and provincial provisions on the repayment of the medical devices' spending ceiling for the years 2015, 2016, 2017 and 2018.

It seems, therefore, that the payback is unstoppable despite the many critical issues, including those of constitutional legitimacy, that discourage medical device suppliers – who have meanwhile also suffered penalising measures such as the unilateral renegotiation of contracts retroactively by public administrations – from working with public health companies.

In order to avert this scenario, which is also problematic for the Health Service itself, there is little alternative but to challenge in court this mechanism by **14 November 2022**.

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