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The activation of payback on medical devices

4 October 2022

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The Italian Ministry of Health, in a Decree dated 6 July 2022, certified the overrun of the expenditure ceiling for medical devices in Italy, at national and regional level.

Companies that have marketed medical devices in Italy at a cost to the national health service (NHS-SSN) during the years 2015, 2016, 2017 and 2018, may soon be required to pay a total amount of approximately 2.08 billion euros. This is unless they manage to effectively challenge (in or out of court) the so-called payback mechanism and the payment demands that will be made by the competent authorities. This is in view of the rules on 'payback relating to medical devices' that have been in force for several years but have so far never been applied in practice.

1. Legal framework

The compensation for exceeding the medical device expenditure ceiling (so-called payback) was introduced in 2011, during a period of severe crisis in the Italian economy and along the lines of the payback introduced in 2008 in relation to overruns of the pharmaceutical expenditure ceiling, which for many years has been the subject of legal disputes that have often led to its significant containment.

Below, we summarise the evolution of the relevant regulatory framework:

- Article 17, paragraph 1, letter c), of Decree-Law No. 98 of 2011 (converted, with amendments, by Law No. 111 of 2011), established that the expenditure incurred by the National Health Service for the purchase of medical devices was to be set within a ceiling, both at the national and regional level, limited to the standard national and regional health requirements, to be defined by subsequent ministerial Decrees. In addition, any repayments were to be assumed by the Regions that had contributed to exceeding the expenditure ceiling.
- pursuant to Article 9-*ter* of Decree-Law No. 78 of 2015 (converted by Law No. 125 of 2015), without prejudice to the national expenditure ceiling set at 4.4% of the National Health Fund[1], part of any overrun of the ceiling must be assumed by the companies that marketed medical devices in Italy in the years in question[2]. In addition, the same provision provided that exceeding the regional expenditure ceiling was to be certified by Decree of the Ministry of Health in agreement with the Ministry of Economy and Finance ("**MEF**") by 30 September of each year, on a provisional basis, and then by 30 September of the following year, on a definitive basis.
- Law No. 145 of 2018 ("**Budget Law 2019**") in Article 1 paragraph 557 provided that the Ministry of Health, in agreement with the MEF, by 30 September of each year shall adopt a Decree certifying the exceeding of the expenditure ceiling, detected based on the turnover of each company before VAT, on the basis of the data resulting from electronic invoicing and relating to the reference calendar year.
- It is important to specify that, pursuant to Article 9-*ter*, paragraph 8, in the execution of contracts there is an obligation to indicate in electronic invoicing separately the cost of the assets and the cost of the service. Payback on medical devices should deal only with the cost of the asset; the cost of the asset should not be included in the cost of the service. The need to separate the prices of the asset and service, without a real ability do so in a unique way, is an additional source of confusion that makes payback on medical devices even more complex than payback on medicinal products.

[1] Art. 1, paragraph 131, lett. b) of Law No. 228 of 2012.
[2] 40% in 2015, 45% in 2016 and 50% from 2017 onwards.

- The Ministry of Health issued a Circular[3] in July 2019 in which it requested the Regional Health Departments to submit a summary statement of the annual turnover per individual medical device supplier for the years 2015-2018.
- In November 2019, two agreements were concluded at the Permanent Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano ("**State-Regions Conference**") by which the regional ceilings were defined for the years 2015-2018 (retroactively), and for 2019, again postponing the completion of the procedure to subsequent implementation measures. These agreements adopted two subsequent administrative acts under the competence of the Ministry of Health. In particular:
  - a first act, to be adopted in agreement with the MEF, certifying the possible exceeding of the expenditure ceiling for medical devices at national and regional level;
  - a second act, to be adopted in agreement with the State-Regions Conference, which defines the procedural methods to proceed with the recovery.

2. Novelties introduced by the Decree of the Ministry of Health of 6 July 2022 and by Decree-Law No. 115 of 2022

Based on the regulations, with the Decree of 6 July 2022 adopted in agreement with the MEF, the Ministry of Health certified the exceeding of the expenditure ceiling for medical devices at a national and regional level for the years 2015, 2016, 2017 and 2018, calculated with reference to the cost data, recorded in final balance for each of the aforementioned years.

The amount of the overrun of the ceiling and the overall share of the recovery to be assumed by the companies supplying the medical devices is indicated, for each year, in the tables attached to the Decree. It is:

- 416.3 million euros for 2015;
- 473.8 million euros for 2016;
- 552.6 million euros for 2017;
- 643.3 million euros for 2018, for a total of just over 2 billion.

The Ministry of Health's Decree of 6 July 2022 was published in the Official Gazette of the Italian Republic on 15 September 2022, a few weeks after the Decree-Law No. 115 of 2022[4] came into force. Article 18 of the Decree provided for a significant **acceleration of the recovery procedures** for the overrun of the expenditure ceiling for medical devices in relation to the **four-year period 2015-2018**. The steps identified by Decree-Law No. 115 of 2022 are listed below:

i The first step is issuing the Decree on the certification of the breach of the expenditure ceiling on medical devices. This step has already been achieved with the publication of the Ministry of Health Decree of 6 July 2022.

ii In the 30 days following the publication of the Decree certifying the breach of the expenditure ceiling, *i.e.* **by 15 October 2022**, the Ministry of Health is asked to adopt, in agreement with the State-Regions Conference, **a further Decree that will dictate the guidelines that Regions and Autonomous Provinces will have to observe** in formulating requests for recovery to the operators concerned. To this end, the State-Regions Conference, which met last 14 September, asked the Government to:

   a identify a central body or ministerial office that, like the Italian Medicines Agency does for the pharmaceutical payback, certify by Region the amounts due to safeguard the entire collection process to reduce possible litigation risk;

   b open a round table with the MEF to define common criteria for risk assessment and for the management of possible litigation;

   c adopt the necessary measures and regulatory changes, including establishing a specific inter-institutional working group, in order to find a rapid definition of a similar method of repayment of the payback for both pharmaceuticals and medical devices, determined on the basis of the amount by which the national and regional ceilings for pharmaceutical expenditure and expenditure for the acquisition of

[3] Prot. 22413 of 29 July 2019.

[4] Converted by Law No. 142 of 2022.

medical devices have been exceeded, in order to ensure the appropriateness of the allocation of available resources in relation to the greater expenditure incurred, to be applied starting from the payback years not yet allocated to the Regions and Autonomous Provinces;

iii Lastly, within 90 days of the publication of the Decree certifying the overrun of the expenditure ceiling, *i.e.* **by 14 December 2022**, the individual Regions and Autonomous Provinces shall be responsible for the task of publishing **the list of companies subject for each year to the mechanism of reimbursement**. The operators concerned shall make **payments to the Regions and Autonomous Provinces within the following 30 days**.

3. Conclusions and counter initiatives

The rules on the payback of medical devices date back to several years ago, when consumption of such products could be considered almost stable or in "normal growth".

The significant increase in healthcare expenditure for such products in the recent past (according to the 2021 Report on public finance coordination of the Court of Auditors amounting to 6.4 % in the financial year 2020 and 2.4 % in the financial year 2019) is mainly linked to the emergency situation related to the COVID-19 pandemic, which led to a considerable increase in the consumption of these products.

These include surgical masks designed to reduce the spread of airborne infection and the pulmonary ventilators used to counter respiratory insufficiency linked to interstitial pneumonia caused by the virus.

Given this, many have questioned whether it would be advisable to review the entire regulatory framework on the payback of medical devices.

In the meantime, however, it is likely that the Regions and Autonomous Provinces will proceed quickly with requests to companies supplying medical devices, to recover the 2.08 billion euros overrun already certified and that a strong reaction from the sector's operators will develop on these requests. Therefore, a significant level of administrative litigation is to be expected, as has already occurred in the past for the payback on medicinal products, with reference to which companies have contested both the legitimacy of the administrative payback measures, as they were adopted on the basis of erroneous or incomprehensible data and calculations as well as the rules themselves that regulate the recovery mechanism.

Regarding the payback of medical devices, the first act that can be challenged is the Decree of the Ministry of Health of 6 July 2022, which certified the exceeding of the expenditure ceiling. The Decree may be **appealed before the Regional Administrative Court** of Latium by **14 November 2022**.

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