

Life Sciences & Healthcare News

- > Medical Devices: payback of medical devices ruling by the Italian Constitutional Court
- > Medical Devices: the new (EU) Regulation 2024/1860, amending the MDR and IVDR, has been published in the EU Official Gazette
- > Italian National Health Service: the Law-Decree to combat, among other things, the problem of waiting lists, has been converted into Law

Medical Devices: payback of medical devices ruling by the Italian Constitutional Court

On 22 July 2024, the Italian Constitutional Court issued two judgements, nos. 139/2024 and 140/2024, concerning the medical devices payback mechanism (Payback). Payback has been established through Article 9-ter of Law-Decree no. 78/2015, in order to give some of the burden of the costs incurred by the Italian Regions for the purchase of medical devices to the suppliers of medical devices to healthcare authorities, over certain financial thresholds.

On one hand, the judgements considered Payback as legitimate and compliant with the Italian constitution, while on the other, they extended the possibility (previously only provided under certain conditions) to all suppliers of medical devices to benefit from a 52% discount on the determined amounts due by each supplier of medical devices by virtue of the Payback mechanism.

Even if Payback was established in 2015, it remained ineffective for seven years. In fact, only in 2022, did Law-Decree no. 115/2022 and a Decree of the Italian Ministry of Health dated 6 October 2022, implement the procedure aimed at quantifying the expenses borne by the Regions for the purchase of medical devices during 2015-2018, in order to determine the Payback amounts due by each supplier of medical devices and therefore making Payback effective.

The Italian Regions issued the resolutions that determined the amounts due according to the national law mentioned above. In 2022 these Regional resolutions were challenged by hundreds of suppliers of medical devices before the Regional Administrative Court of Lazio – Rome (TAR Lazio), claiming – *inter alia* – that the Payback regulation is in breach of the Italian Constitution. During the pending proceedings, TAR Lazio referred the decision regarding compliance of the Payback regulation with the Italian Constitution, to the Italian Constitutional Court.

While the proceedings mentioned above were pending, the new Law-Decree no. 34/2023 established a state fund, to be allocated on a pro-quota basis to the Regions that had exceeded the spending cap during 2015-2018, allowing suppliers of medical devices involved in the application of the Payback to only pay 48% of the Payback amount initially requested to them by the Regions, provided that on their own free will, they waived the proceedings initiated before TAR Lazio, as well as their right to future challenges in Court regarding the resolutions concerning the 2015-2018 Payback.

Campania Region challenged Law-Decree no. 34/2023 before the Italian Constitutional Court claiming that it breaches the Italian Constitution.

On 22 July 2024, the Italian Constitutional Court declared:

- i. through Judgment no. 140/2024, that the questions of constitutionality of Law-Decree no. 78/2015 were ungrounded and stated the legitimacy of the Payback. The Italian Constitutional Court motivated the decision stating that the Payback is a proportionate and reasonable measure;
- ii. through Judgment no. 139/2024, that the provisions of Law-Decree no. 34/2023 are non-constitutional, insofar as they do not extend the reduction to 48% of the Payback amount originally determined by the Regions to all medical device supply companies.

As a result of these two judgements, all companies will have to pay the amounts due by virtue of the Payback mechanism, but they can now benefit from the reduced payment (as stated in Judgment no. 139/2024) without having to waive the pending legal actions nor the right to future challenges in Court regarding the resolutions concerning the 2015-2018 Payback.

In fact, the pending proceedings will now have to be decided by TAR Lazio on the basis of the grounds of appeal against the Regional resolutions concerning, for example, the lack of a proper investigation of the Regions on the amount due by the suppliers of medical devices, as well as certain procedural flaws or computational errors.

With regards to the future, Article 9-*ter* of Law-Decree no. 78/2015 provides that Payback shall operate for every year in which the spending cap of the Regions for the purchase of medical devices is exceeded. Therefore, the Payback mechanism is destined to operate indefinitely, unless it is repealed or amended by law.

Medical Devices: the new (EU) Regulation 2024/1860, amending the MDR and IVDR, has been published in the EU Official Gazette

On 9 July 2024, a new Regulation amending the (EU) Regulations 2017/745 (MDR) and 2017/746 (IVDR) was published in the EU Official Gazette.

The new Regulation (a) modifies certain provisions of the MDR and of the IVDR concerning the European database of medical devices (so called Eudamed); (b) introduces protective measures in case of interruption or discontinuation in the supply of medical devices; and (c) extends the interim period for the *in vitro* devices manufactured in compliance with the previous regulatory framework provided by EU Directive 98/79/CE (so called Legacy devices).

In particular, the new Regulation provides:

- i. that the obligations of the economic operators relating to Eudamed (which is made up of several "modules" and, as of today, is not yet completely operational) will come into effect progressively (*i.e.*, the economic operators will have to register in each Eudamed module once that single module becomes available);
- ii. the introduction of Article 10-*bis* in both MDR and IVDR, providing that where a manufacturer foresees an interruption or a discontinuation of the supply of a medical device and it is reasonable to assume that such interruption or discontinuation could result in serious harm (or risk of serious harm) to patients or public health, the manufacturer shall inform – at least six months before the interruption/discontinuation – the competent authority of the Member States in which it is established, as well as the economic operators that market its medical devices;
- iii. the extension of the interim period of the IVDR for the devices manufactured in compliance with the previous regulation. In fact, thanks to the new provisions, the manufacturers of *in vitro* Legacy devices will be able to place such devices on the market until 31 December 2027, 31 December 2028 and 31 December 2029, depending on the risk classification of the device.

Pursuant to Article 3 of the new Regulation, the provisions described above under (i) and (iii) have come into force on 9 July 2024, while the provision described under (ii) will come into force on 10 January 2025.

Italian National Health Service (NHS): the Law-Decree to combat, among other things, the problem of waiting lists, has been converted into Law

On 31 July 2024 Law no. 107/2024, converting Law-Decree no. 73/2024 was published in the Italian Official Gazette. Such Law-Decree has been adopted to combat, among other things, the problem of NHS' waiting lists.

The conversion Law has basically confirmed the provisions set forth in the converted Law-Decree and only made minor changes (some of which are highlighted below in bold). The new set of rules to combat the problem of NHS' waiting lists includes:

- > the creation of a national platform for waiting lists run by AGENAS (the Italian National Agency for Regional Healthcare Services), which will monitor the timing of delivery of healthcare services among different Regions;
- > **the creation of a new public entity that will monitor and audit the local healthcare authorities, public healthcare structures and private healthcare structures (reimbursed by the NHS) to verify and analyse possible dysfunctions in the delivery of healthcare services;**
- > the creation of a single regional or infra-regional reservation centre (so called CUP) that will gather all the available public healthcare structures and private ones which are subject to public reimbursement;
- > a system to remind the patient of the reservation of the medical examination, that will also give the patient the chance to cancel the reservation. **Furthermore, the patients who fail to show up (without justification) on the day of the medical examination may be charged for the cost of the medical examination;**
- > a system aimed at ensuring that the requested medical service will be provided by the NHS within a certain time (depending on the gravity of the illness). In the event such timing is not respected, private healthcare structures reimbursed by the NHS will provide the medical service;
- > the possibility of carrying out medical examinations during the weekend;
- > an increase of the spending cap for the recruitment of healthcare personnel in 2024 and the abolition of such cap starting from 2025;
- > a flat-tax of 15% for overtime carried out by doctors, independent from the total income of the healthcare professional.

The Law came into force on 1 August 2024. Therefore, it will take some time to see whether the Law will solve the NHS waiting list problems.



Legance

Contacts

healthcare@legance.it

Edited by

Legance

www.legance.com

Graphic Design

VitamineD

