Legance

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PHARMACEUTICAL AND MEDICAL DEVICE EXPENDITURE MEASURES IN THE 2026 BUDGET LAW AND THE REVISION OF PAYBACK MECHANISMS UNDER THE CONSOLIDATED PHARMACEUTICAL LEGISLATION

*Law No. 199/2025 ("**2026 Budget Law**") raises the expenditure thresholds for pharmaceuticals and medical devices reimbursable by the National Health Service (NHS) with the aim of partially addressing the magnitude of budget overruns and, consequently, the contribution required from pharmaceutical companies and medical device suppliers under the payback mechanism.*

Effective as of 1 January 2026:

- The **national expenditure threshold for the purchase of medical devices** will be increased from 4.4% to 4.6% of the National Health Fund ("**NHF**");
- The **expenditure threshold for direct pharmaceutical purchases** (*Spesa per acquisti diretti*) will be raised by 0.30%, from 8.5% to 8.8% of the NHF;
- The **national threshold** for reimbursed pharmaceutical expenditure by **pharmacies** (*Spesa convenzionata*) will increase marginally by 0.05%, from 6.8% to 6.85% of the NHF;
- The **expenditure threshold for medicinal gases** remains unchanged at 0.2%, in consideration of the stability of volumes and procurement costs.

While these threshold increases are appreciable, they lag behind the actual growth in pharmaceutical and medical device expenditure recorded by the Court of Auditors in September 2025 (please see *Quaderni del Rapporto sul Coordinamento della finanza pubblica*, Quaderno No. 4 – *La sanità in cammino per il cambiamento*), and overspending risks remain unless more effective compensation mechanisms are introduced.

In the medical devices' sector, the heavy impact of the payback mechanism on operators for the 2019–2024 period remains a major concern. The Court of Auditors, simulating a scenario under current legislation, estimated an **overspending of approximately Euro 10.5 billion**, with **payback obligations on medical device suppliers amounting to roughly Euro 5.2 billion**, to which the estimated 2025 obligations will be added.

Further revisions to expenditure thresholds and payback rules are currently under government review.

On 18 September 2025, the Council

of Ministers approved a delegated bill (*disegno di legge delega*) concerning the "Reorganisation of Pharmaceutical Legislation" ("**Consolidated Pharmaceutical Legislation**") with the objective of simplifying, rationalising, and enhancing the effectiveness of the sector's complex regulatory framework.

The Consolidated Pharmaceutical Legislation, currently under discussion in Parliament, authorises the Government to adopt, by 31 December 2026, one or more legislative decrees for the reorganisation, revision, and rationalisation of the provisions governing the pharmaceutical sector through the drafting of consolidated texts. Among the specific guiding principles of this delegation, under Article 3, letter b), are:

- The **adjustment or revision of pharmaceutical expenditure thresholds**, and
- The **revision of payback mechanisms**.

ABOLITION OF THE 1.83% PAYBACK AND REINSTATEMENT OF THE 5% PRICE REDUCTION UNDER THE 2026 BUDGET LAW

Under Article 1, paragraph 389, of the 2026 Budget Law, effective 1 January 2026, ***pharmaceutical companies are no longer required to pay the 1.83% payback*** *to the Regions on the retail price of medicines reimbursed by the National Health Service (NHS) under the conventional distribution regime set out in Article 11, paragraph 6, of Decree-Law No. 78/2010.*

This measure aims to reduce the financial burden on the pharmaceutical industry and limit administrative litigation, effectively removing one of the main *ex-post* compensation mechanisms for pharmaceutical expenditure overruns.

Pursuant to Article 1, paragraph 395, the 2026 Budget Law also **repeals the provisions that allowed marketing authorisation holders to suspend the mandatory 5% reduction of the retail price of medicines reimbursed by the NHS** in exchange for a corresponding payback payment to accounts indicated by the Regions, previously provided for under Law No. 296/2006.

Impact as of 1 January 2026:

- Pharmaceutical companies can no longer suspend the mandatory 5% reduction on the retail price of NHS-reimbursed medicines;
- The option to replace the price reduction with alternative compensatory mechanisms is removed;
- The system effectively re-establishes a forced price deflation model for medicines reimbursed by the NHS.

THE FUTURE OF ACCESSIBLE DIGITAL HEALTHCARE: INSIGHTS FROM THE NEW AGID GUIDELINES

*On 11 March 2026, with the adoption of the new "Guidelines on the Accessibility of Digital Services" (the "**Guidelines**") by the Agency for Digital Italy ("**AgID**"), Italy took another step toward implementing Article 21 of Legislative Decree No. 82/2022 (the "**Accessibility Decree**"), fully incorporating the principles of the European Accessibility Act (Directive (EU) 2019/882).*

According to the Accessibility Decree, providers of digital services must implement solutions that ensure full accessibility **throughout the entire service delivery cycle**, guaranteeing the service's ongoing compliance, including:

i. ensuring that the services provided are accessible (through appropriate fonts, sizes, and display methods), providing users with clear, perceivable information available across multiple sensory channels;
ii. making the web sites and mobile applications through which the services are provided accessible in a consistent and adequate manner, ensuring they are perceivable;
iii. promoting support services (service desks, call centers, technical support, etc.) that provide information regarding the accessibility of the services.

The scope of the Accessibility Decree and of the Guidelines includes providers of certain digital services **that could be delivered in the healthcare sector**, including:

a. subtitles for the deaf and hard of hearing, **audio descriptions**, **spoken subtitles**, and sign language interpretation, resulting from the implementation of measures to make services accessible to all;
b. e-commerce services provided by the provider via the web or app for the conclusion of contracts with consumers.

The Guidelines provide operational guidance and clarification on accessibility requirements, as already established by the Accessibility Decree. The importance of the fundamental principles of digital accessibility is reiterated, particularly the POUR principles (Perceivable, Operable, Understandable, Robust), considered the international benchmark. The Guidelines also refer to the international ISO/IEC standards and the Web Content Accessibility Guidelines (WCAG).

The key date remains 28 June 2025, already established by the Accessibility Decree, from which digital products and services covered by the decree must comply with the accessibility requirements.

The Guidelines reiterate the exemptions already established by the decree:

i. products already in use for the provision of the relevant services may be retained until **28 June 2030**;
ii. contracts concluded before 28 June 2025 will remain valid until their expiry, for a **maximum of 5 years**;
iii. self-service terminals (*e.g.*, hospital kiosks) may be used until the end of their economic life, but in any case, **no later than 20 years after commissioning**.

The Guidelines clarify the meaning of the exemptions provided for in Article 13, paragraph 1, of the Accessibility Decree, pursuant to which accessibility requirements apply only if they do not entail:

a. substantial modification of the service, *i.e.* an intervention that affects the service's structural characteristics or functionalities/interfaces; or
b. disproportionate burden on the operator, *i.e.* an organisational or financial burden which could jeopardise the service's objectives, considering multiple parameters, including the costs to be incurred balanced with the expected benefits for users (particularly in the use of essential services, such as healthcare).

The Guidelines also provide certain recommendations regarding governance for the management of accessibility issues, including the establishment of a dedicated compliance function (for large organisations) or the designation of an accessibility contact person (particularly for SMEs) responsible for liaising with users and AgID in the event of complaints and/or requests for information.

Finally, the Guidelines confirm the requirements set out in the Accessibility Decree that must be met to qualify for the exemptions provided. These include **carrying out a documented assessment** - to be retained for five years from the last provision of the service and periodically updated (annually and/or whenever the service is modified) - as well as **notifying AgID of the decision taken. Please note that the disproportionate burden exemption cannot be invoked where public or private funding has been allocated for accessibility purposes**.

THE UPC TRANSITIONAL REGIME, VENICE COURT'S 12 NOVEMBER 2025 JUDGMENT AND ITS IMPLICATIONS FOR THE PHARMACEUTICAL SECTOR

*With the **entry into operation of the Unified Patent Court** ("**UPC**"), a significant portion of European patent litigation is no longer intended to be conducted exclusively before the national courts of the individual States, but is instead assigned to a court common to the States participating in the system.*

As a rule, the UPC has exclusive jurisdiction over civil disputes relating to unitary patents, European patents and supplementary protection certificates, including infringement actions, declarations of non-infringement, revocation and invalidity actions, as well as applications for provisional measures.
However, **the UPC system does not apply in a rigorous manner to "classic" European patents**. **Article 83 of the Agreement on a Unified Patent Court** (in force since 1 June 2023, the "**UPCA**") provides, for a transitional period of seven years:

i. actions relating to "classic" European patents and supplementary protection certificates ("**SPCs**") may still also be brought before national courts; and
ii. the proprietor of a "classic" patent or SPC may exercise the opt-out, *i.e.* choose to exclude the title from the jurisdiction of the UPC and keep it within the scope of national jurisdictions.

The transitional period is generally understood as a phase of coexistence between the UPC and national courts, during which the national route remains available for "classic" European patents and related SPCs.
In this context, **the opt-out serves as a formal mechanism to exclude the title from the jurisdiction of the UPC**, with effects that can also be known by third parties through registration in the relevant register.
From an operational standpoint, the system would therefore appear to be structured on two levels:

i. the continued possibility, during the transitional period, of bringing actions before national courts as well; and
ii. the proprietor's right to remove the title from UPC's jurisdiction (opt-out).

This approach has also been confirmed by the 2026 Unitary Patent Guidelines, which specifically refer to the coexistence of UPC jurisdiction and national jurisdiction until 31 May 2030, unless an opt-out is exercised.

It is background this context that **the decision of the Venice Court dated 12 November 2025** must be considered.
The Court raised the issue of jurisdiction *ex officio* in relation to a European patent and held that, **in the absence of an opt-out, the title remained subject to the jurisdiction of the UPC**.
Based on that, the Court declared that the national court lacked jurisdiction in relation to the claim based on the European patent.
The reasoning followed by the Venice Court is built around a precise idea: the default rule would be that a European patent falls within the jurisdiction of the UPC, while the opt-out would constitute the only mechanism capable of excluding such jurisdiction. From this perspective, registration of the opt-out in the register plays a vital role in certainty and transparency for the market and potential defendants.
According to this approach, **the "concurrent" jurisdiction envisaged during the transitional period would not grant the proprietor freedom to choose, on a case-by-case basis, between a national forum and the UPC**. In the Court's view, such a possibility would create uncertainty and reduce the predictability of the system.
The Venice Court's interpretation appears more restrictive than the one many practitioners had inferred from the text of the UPCA and from the official guidance itself. From this perspective, **the opt-out would not merely operate as a mechanism to exclude the UPC, but would, in practice become the condition necessary to keep litigation before the national court**.
The practical implications are particularly significant for the pharmaceutical sector. Although the Venice case did not directly concern a SPC, the specific reference to European patents and supplementary protection certificates in Articles 32 and 83 UPCA suggests that the issue is not confined to basic patents. For companies, the decision whether to keep a title inside or outside the UPC system therefore becomes a strategic assessment to be addressed *ex ante*, and not only once a dispute has arisen.

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