New National Health Technology Assessment System

Decree-Law No. 118/2026

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Decree-Law No. 118/2026, published on 17 June, approves the new National Health Technology Assessment System ("SiNATS").

Originally created in 2015 by Decree-Law No. 97/2015, of 1 June, SiNATS has operated as a strategic decision-making tool within the National Health Service ("NHS"), supporting the adoption of health technologies with added value, equitable access to healthcare and the financial sustainability of the system.

Ten years on, the development of health technologies, changes in the healthcare system and the introduction of a European health technology assessment framework under Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment ("HTA Regulation") have made a comprehensive update necessary.

The reform reflects major scientific and technological developments in medicines, medical devices and other health technologies, including precision medicine, complex advanced therapies, digital systems, artificial intelligence-based solutions, combination products and the growing interdependence between different technologies.

The changes are extensive and particularly relevant for companies operating in the life sciences and healthcare sectors. The key highlights are set out below.

Integration of the HTA Regulation into national law

One of the main structural changes is the alignment of the new SiNATS with the HTA Regulation. Unlike the 2015 framework, which was exclusively national, the new regime addresses joint clinical assessments, joint scientific consultations, the identification of emerging technologies and the powers of the Member State Coordination Group, with INFARMED, I.P. designated as the national authority responsible for the application of the HTA Regulation.

The new SiNATS also prevents health technology holders from being asked to resubmit information or documentation already provided in European health technology assessment procedures, reducing duplicative administrative burdens that have often contributed to delays.

Specific reference to digital technologies and artificial intelligence

Another important development is the strengthening of health technology assessment other than medicines.

Medical devices are given particular prominence, reflecting their increasing complexity, their combination with medicines and the integration of software and artificial intelligence tools. The new regime expressly brings software and artificial intelligence solutions within the scope of technologies subject to assessment.

Data and interoperability

The new framework places greater emphasis on information generated in real-world clinical settings, including routine-use data as well as administrative and clinical records.

In this context, the Decree-Law establishes a legal basis ensuring that INFARMED, I.P. can have effective and timely access to information relating to health, prescriptions, consumption and expenditure.

This access is implemented through the interconnection of the various databases, records and information platforms of the entities supervised by the Ministry of Health, in accordance with the principles of data protection and security enshrined in the framework of the European Health Data Space, established by Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space.

The Information System for Assessment and Access ("SIATS") is also reformulated and significantly strengthened. It will now centralise information relevant to health technology assessment through data received from public and private entities.

Prices of health technologies

The new regime maintains the framework for setting maximum prices for prescription-only medicines for human use dispensed in community pharmacies. It also extends this framework to non-prescription medicines where they benefit from public availability or where public health protection so requires.

As regards medical devices and other health technologies, the statute opens the possibility of applying maximum price limits in the context of public availability.

For the purpose of setting such prices, the use, among other methods, of historical analysis of the values actually applied by NHS establishments and services and by the outpatient market is permitted.

Formal separation between clinical and economic evaluation

Clinical and economic evaluation were treated under the previous regime in a relatively unified manner.

The new regime separates the assessment process into two sequential and autonomous phases. Clinical assessment continues to precede economic assessment, but the new framework introduces "added clinical value" as a central concept and adopts the PICO methodology (Population, Intervention, Comparator and Outcomes). The definition of PICO will involve a participatory process including patient associations, which is also a relevant innovation.

Reimbursement tiers set directly by law

Under the new statute, the reimbursement tiers are now set directly by law, while the tiers previously established remain unchanged.

The statute also provides for an increase of 5% in tier A and 15% in tiers B, C and D for low-income pensioners meeting certain conditions.

In such cases, State reimbursement may reach 95% across all tiers.

Reimbursement tiers for medical devices are also established, in the amount of 75%, 35% and 15%.

More demanding and detailed pricing regime for generics and biosimilars

The new regime incorporates price reduction rules for generic medicines directly into the statute.

Thus, the retail price of a generic medicine must be at least 50% lower than that of the reference medicine or, where the wholesale price of the reference medicine is below EUR 10, at least 25% lower.

For reimbursement purposes, from the sixth generic medicine onwards, the maximum retail price must be 3% lower than that of the generic medicine in respect of which the immediately preceding valid reimbursement application was submitted.

New criteria for demonstrating economic advantage

The criteria for demonstrating economic advantage are substantially reformulated and linked to the clinical classification assigned to the technology.

Medicines with no added therapeutic value will now require a minimum price reduction of 10%, while specific rules are also introduced for fixed combinations and a maximum threshold of 5% for situations where the added value is not quantifiable.

New access mechanisms and clinical governance

The statute creates a prospective health technology identification system (horizon scanning) to identify, at an early stage, innovations with the potential to transform clinical practice.

Based on this system, assessment may be prioritised according to criteria such as the existence of unmet medical needs, the pioneering nature of the technology in a new therapeutic area, or its potential disruptive impact for patients or for the NHS.

The new regime also introduces scientific advice for holders, strengthens the role of the National Pharmacy and Therapeutics Committee in defining therapeutic positioning and managing the National Medicines Formulary, creates the Exceptional Availability Regime and establishes a pilot programme for simultaneous assessment for marketing authorisation and public availability.

Assessment timelines expressly provided for

Assessment timelines are now expressly provided for in the statute.

Under the previous regime, these timelines were largely left to supplementary regulation, notably the ministerial orders that regulated the regime.

Price confidentiality and mandatory renegotiation

Reflecting existing practice, the new regime expressly allows public availability contracts for health technologies to include confidentiality clauses covering prices, discounts and risk-sharing models.

This is already a widely used practice, but one that lacked an express legal basis. The confidentiality framework now established also extends to reimbursement and/or prior assessment agreements entered before the new regime came into force.

The statute also introduces mandatory renegotiation, with a minimum reduction of 10%, where the covered population or State expenditure associated with the health technology increases by more than 60% compared with the previously agreed expenditure cap.

Transparency, public participation and conflicts of interest

The new SiNATS also formalises the structured participation of patient associations in assessment procedures and requires annual declarations of interests from those involved in health technology assessment, in line with the HTA Regulation.

Reformulated administrative offence regime

Although the amount of the fines is maintained, the catalogue of infringements is reformulated to reflect the new duties established by the statute, including those relating to evidence submission, market supply, price confidentiality and other obligations under the new regime.
Transitional regime

The new regime does not apply to public availability applications pending on the date of its entry into force.

However, it applies to health technology reassessment procedures and to reviews of contracts entered under the previous SiNATS. References in legislation to the previous regime should be read as references to the corresponding provisions of the new regime.
The statute enters into force on 1 July 2026.

Thinking about tomorrow? Let's talk today.

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