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New SiNATS: impact on market access, real-world data and European alignment

New Decree-Law No. 118/2026 of 17 June

Decree-Law No. 118/2026, of 17 June, substantially revises the National Health Technology Assessment System (SiNATS), integrates the new European health technology assessment framework and repeals Decree-Law No. 97/2015.

Key elements of the reform

1 - Full integration with the new European HTA system

SiNATS will formally incorporate the application of Regulation (EU) 2021/2282, using joint clinical assessments conducted at EU level as the basis for national decisions on added clinical value and funding.

2 - Enhanced governance, transparency and stakeholder participation

INFARMED is reaffirmed as the manager of SiNATS, with the roles of CATS and CNFT strengthened in respect of therapeutic positioning and the National Medicines Formulary. The legislation establishes a structured framework for the participation of patient associations, consumer groups, healthcare professionals and industry, supported by reinforced rules on independence and conflicts of interest.

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3 -Data, SIATS and real-world evidence

SIATS will no longer function merely as an information repository; it will become the central platform for submission, process management, monitoring of use and data sharing with other NHS systems, in line with the European Health Data Space. The use of real-world data becomes a key component in the assessment and reassessment of health technologies.

4 - Pricing, reimbursement and contracting

The existing logic of maximum prices with international reference pricing and contracting with INFARMED is maintained, but with more detailed rules for generics and biosimilars — including minimum discounts on the maximum retail price relative to the reference medicine and near-automatic market access mechanisms where certain pricing criteria are met.

5 - Timelines and special access schemes

The legislation sets maximum assessment and decision timelines, differentiated according to the type of technology and the existence of a joint European clinical assessment, and provides for exceptional availability schemes (early access) and special schemes by pathology or patient group, to be further defined by ministerial order.

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This reform forms part of the "Medicines Package" announced by the Government on 9 April 2026, aimed at modernising pricing, reimbursement and access to innovation. It enters into force on 1 July 2026.

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