

ROSIA PCP

INSIGHTS FROM THE POLICY WORKSHOP



Challenges on prescription and reimbursement of digital therapeutics in Europe



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INSIGHTS FROM THE POLICY WORKSHOP



A standard alone is not enough

Europe needs a living system for continuous evaluation and monitoring of digital therapeutics, especially as solutions evolve rapidly and integrate AI.

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Fragmentation remains a major barrier

27 different regulatory and reimbursement pathways make scaling a digital solution in Europe disproportionately costly, especially for startups and SMEs.

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Industry asks for three things:

Clear evaluation criteria, predictable timelines, and flexible frameworks that enable the use of real-world data and support iterative development.



High Standards, More Agility

Europe must maintain its high standards on privacy, safety and patient protection, but we urgently need more agile processes, less duplication, and mutual recognition of evidence across Member States.

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