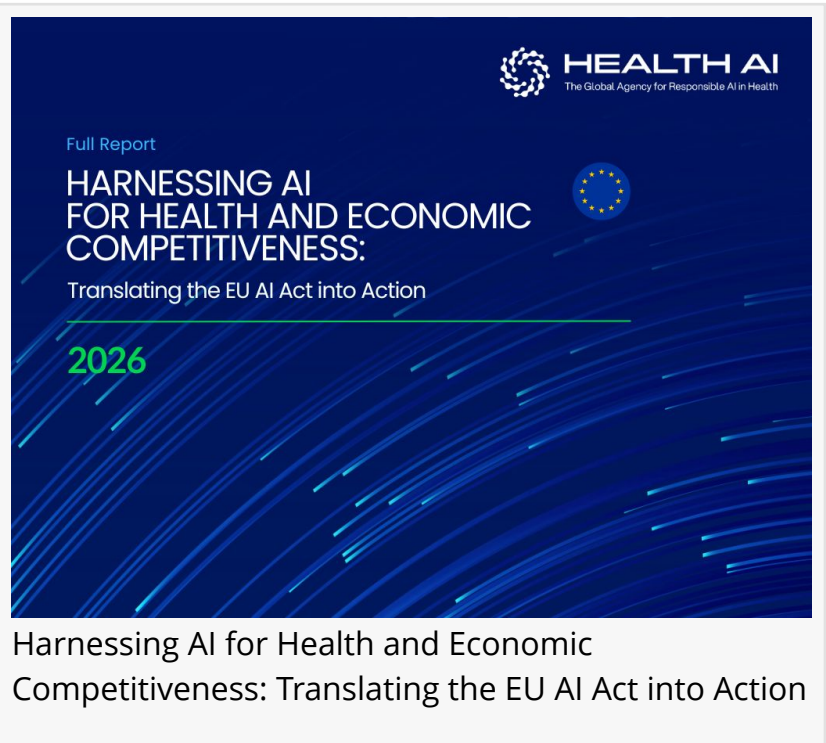


# HealthAI Launches Report on EU AI Act Implementation for Health & Competitiveness

*In "Harnessing AI for Health and Economic Competitiveness," HealthAI translated the EU AI Act into Action for Responsible AI in Health.*

GENEVA, SWITZERLAND, May 19, 2026 /EINPresswire.com/ -- [HealthAI - The Global Agency for Responsible AI in Health](#), unveils "Harnessing AI for Health and Economic Competitiveness: Translating the EU AI Act into Action," a strategic analysis of the European Union's regulatory framework for artificial intelligence in health. The report, launched during the World Economic Forum's Annual Health Roundtable on the margins of the 79th World Health Assembly, provides critical implementation guidance as Europe's four largest economies navigate the intersection of AI innovation and regulatory compliance.



The report examines implementation challenges and opportunities across the European Commission and four Member States: Germany, France, Italy, and Spain. Drawing on 20 semi-structured stakeholder consultations, expert dialogues at the European Health Forum Gastein, and policy analysis conducted between October 2025 and April 2026, the report delivers actionable recommendations to improve institutional coordination and enforcement capacity for the AI Act's implementation.

"The EU has matched ambitious regulatory frameworks with significant policy architecture designed to position Europe as a competitive global AI leader," said Dr. Ricardo Baptista Leite, CEO of HealthAI. "However, our analysis identifies a critical implementation gap: the infrastructure required to support compliance obligations is arriving later than the deadlines themselves. This report provides the strategic roadmap to navigate that complexity and transform regulatory requirements into a competitive advantage."

The report reveals a consistent pattern across the EU's regulatory landscape: while harmonized



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*Dr. Ricardo Baptista Leite,  
CEO of HealthAI*

standards, notified body capacity, and support mechanisms remain incomplete, compliance obligations are taking effect. Key findings include:

- Implementation infrastructure lags behind compliance timelines: Essential support measures - including guidelines on the AI Act's interplay with medical device regulations, the European Network of Expertise on AI Deployment in Healthcare, and full operationalization of the European Health Data Space - are scheduled to materialize after, or concurrently with, the high-risk provisions taking effect.

- Notified body capacity presents a critical bottleneck: As of October 2025, 51 notified bodies have been designated under the Medical Device Regulation, but AI Act designation requires demonstrating additional competencies in AI technology and data science that extend beyond traditional assessment capabilities.

- National implementation priorities diverge significantly: France, Germany, Italy, and Spain are advancing implementation through distinct institutional models. Spain has established Europe's first AI supervisory agency (AESIA) and launched the continent's first regulatory sandbox; Italy enacted the EU's first comprehensive national AI law; Germany is pursuing dedicated implementation legislation; and France is embedding AI governance within established health regulation frameworks.

- Coordination between horizontal and sectoral authorities remains untested: No country has yet validated its proposed dual supervision model—balancing horizontal AI authorities with sector-specific medical device regulators—in practice, creating enforcement uncertainty.

- Market access, not market authorization, may constrain innovation: Only Germany and France have structured reimbursement pathways that can help scale AI tools in clinical settings, while approved technologies in Spain and Italy often lack the budgetary and legal basis for adoption.

The report delivers five strategic recommendations:

- Test dual supervision architectures before high-risk requirements take effect: Countries should conduct joint exercises between AI authorities and medical device regulators to identify conflicts and operational gaps.

- Address regulatory barriers to SME market access and scaling: Prioritize harmonized reimbursement pathways across the EU so regulatory approval translates into clinical use.

- Clarify the interplay between the European Health Data Space, the AI Act, and medical device regulation: The European Commission should provide coordination instruments, including blueprints and roadmaps, to guide stakeholders through the parallel regulatory frameworks ahead of enforcement deadlines.
- Formalize channels for knowledge exchange on implementation: Member States should leverage each country's comparative strengths through structured peer learning, facilitated by DG SANTE and the AI Office.
- Ensure coordination extends to structured multistakeholder engagement at the EU and national levels: Implementation decisions on oversight structures, conformity assessment procedures, and enforcement priorities must incorporate the perspectives of those affected.

Developed in collaboration with strategic partners, including the World Economic Forum, Friends of Europe, UNITE Parliamentarians Network for Global Health, the European Health Forum Gastein, and with the kind support of Roche and Philips, the report marks a significant milestone in HealthAI's mission to serve as the global implementation partner for responsible AI governance in health.

Amanda Leal, AI Governance & Policy Specialist at HealthAI, and lead author of this work, said about the report: "Building on HealthAI's expertise working with national governments, we focus our analysis on two crucial elements for successful AI governance implementation in health: institutional coordination and enforcement capacity. While the European Union is in the right direction with its policies and ambitions, we point out concrete measures to strengthen implementation readiness."

The report is available for download at [www.healthai.agency](http://www.healthai.agency)

Stéphane Dupré

HealthAI - the Global Agency for Responsible AI in Health

[communication@healthai.agency](mailto:communication@healthai.agency)

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