Europe's health innovation needs true digital simplification

MedTech Europe's response to the publication of the Digital Omnibus package

20 November 2025

Medtech Europe acknowledges the publication of the Digital Omnibus package by the European Commission and calls on policymakers to ensure this initiative truly simplifies and clarifies digital regulations for Europe's medical technology sector.

The Digital Omnibus seeks to streamline the EU's complex digital legislative framework, addressing concerns about overlapping and fragmented compliance requirements. For the medical technology sector, including connected devices, diagnostic software, and AI-driven solutions, these challenges are significant. Yet, **innovation and patient access to cutting-edge solutions are hindered by unclear, fragmented or duplicative rules layered over existing sectoral legislation**.

MedTech Europe welcomes the European Commission's intent to simplify digital legislation but urges for the package to go further to safeguard Europe's leadership in medical innovation.

The Digital Omnibus on AI Proposal, marks a strategic update to the AI Act[1]. While MedTech Europe welcomes clarity regarding the interplay with the Cyber Resilience Act[2], we urge policymakers to ensure coherence with existing sectoral legislation (Medical Devices Regulation (MDR)[3] and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)[4]). We acknowledge the positive intent behind proposed amendments to establish a legal avenue for pre-market testing as well as a unified application and assessment procedure for Notified Bodies under the AI Act, aiming to streamline and expedite designations while maintaining compliance with both the AI Act and existing Union harmonisation legislation. At the same time, we wish to emphasise that it will be critical to further refine key definitions, particularly that of *"substantial modification"*, during the upcoming legislative process. Finally, while we welcome the introduction of a conditional mechanism for the application of legal requirements for Annex I AI systems, with a latest possible entry into application on 2 August 2028, we urge policymakers to further adjust this timeline. Extending the full application date for AI-enabled medical technologies to 2 August 2029 would better reflect the regulatory ecosystem's readiness.

Regarding the Digital Omnibus on the data acquis, MedTech Europe takes note with interest of the inclusion of aspects of the General Data Protection Regulation (GDPR)[5] within the scope of the forthcoming proposal, as an important step toward greater coherence and clarity in the EU's digital regulatory landscape. The medical technology industry supports the overarching objectives of protecting individuals' rights and fostering trust in digital health innovation. At the same time, we recognise the opportunity to address persistent challenges such as fragmented interpretations, overlapping frameworks, and inconsistent terminology across existing legislation.

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[1] AI Act Regulation (EU) 2024/1689
[2] Cyber Resilience Act Regulation (EU) 2024/2847
[3] Medical Devices Regulation (EU) 2017/745
[4] *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746
[5] General Data Protection Regulation (EU) 2016/679

The Digital Omnibus also seeks to consolidate provisions from the Data Act[6], Data Governance Act[7], Free Flow of Data Regulation[8], and Open Data Directive[9]. While MedTech Europe supports the objective of simplification and clarification, merging of these rules may not resolve all of the concerns nor should it not inadvertently introduce greater complexity. Concerning the Data Act, the proposal lacks a proportionate and sector-specific approach to health data sharing under the European Health Data Space (EHDS), failing to adequately account for the unique sensitivity of health data. We remain convinced it is needed to create an environment that allows for meaningful data sharing with patients and healthcare professionals to enhance healthcare delivery via a sector-specific framework (such as the EHDS), while ensuring legal clarity and avoiding potential overlaps or unintended consequences stemming from the horizontal provisions of the Data Act. We acknowledge the intent to enhance safeguards to protect trade secrets and supplement existing provisions under the Data Act. In this regard, we also ask to reconsider the requirement to demonstrate a risk o*f 'serious economic damage',* as this imposes an undue burden on companies seeking to protect sensitive information. Instead, we recommend levelling the protection of trade secrets and security protections in the Data Act with international standards. Finally, the proposal does not adjust the Data Act's application date or provide stakeholders with sufficient preparation time, undermining legal certainty, and practical feasibility.

"Simplification is not about lowering standards. It is about making compliance more efficient and predictable, so innovations reach patients and health systems faster. An effective Digital Omnibus must align all relevant digital laws, provide clear guidance, and support harmonised implementation across Member States," said Alexander Olbrechts, Director Digital Health at MedTech Europe.

Real reforms should not be postponed to the Digital Fitness Check[10] expected in 2027. As highlighted in MedTech Europe's input to the recent call for evidence, predictability is essential for the medical technology sector. MedTech Europe stands ready to collaborate with policymakers to make the Digital Simplification Package a cornerstone of Europe's technological sovereignty and competitiveness, ultimately enabling faster access to safe and innovative medical technologies for patients and health systems across the EU.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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6 Data Act Regulation (EU) 2023/2854
7 Data Governance Act Regulation (EU) 2022/868
8 Free Flow of Data Regulation (EU) 2024/1689
9 Open Data Directive (EU) 2019/1024
10 Digital Fitness Check - testing the cumulative impact of the EU's digital rules