MedTech Europe response to public consultation on the draft text of the EU Merger Guidelines

June 2026

Introduction

MedTech Europe welcomes the European Commission's initiative to revise the EU Merger Guidelines[1] to better reflect evolving market realities, including innovation, digitalisation, and the increasing relevance of ecosystem-based competition. We appreciate the Commission's effort to modernise the analytical framework and provide greater guidance on how complex, innovation-driven markets will be assessed, particularly with respect to innovation, potential competition, and interconnected products.

As the European trade association representing the medical technology ("medtech") industry, **MedTech Europe represents a highly regulated, research-intensive sector that plays a critical role in Europe's healthcare systems**. The medtech sector develops medical devices, diagnostics and digital health solutions that support patient care, and has a strong interest in ensuring that the revised Guidelines support both effective competition enforcement and continued innovation.

While we support the Commission's forward-looking approach, several elements of the draft raise concerns as they risk encouraging overly speculative assessments and reducing legal certainty. These risks are particularly pronounced in highly regulated, innovation-driven sectors such as medtech, where long development cycles, regulatory requirements, and clinical considerations fundamentally shape competitive dynamics.

Key considerations for the application of the Draft Guidelines to the medtech sector

Risk of overly speculative enforcement (Part I.B; Part II.B.3-5)

Across multiple sections, the draft Guidelines introduce expanded theories of harm, including loss of innovation competition, loss of potential competition, loss of investment and expansion competition, and ecosystem-related foreclosure (see in particular *§§169–207 and §§208–251*). While these developments aim to capture modern competitive dynamics, their current formulation risks lowering the evidentiary threshold for intervention, increasing the likelihood of false positives, and placing undue reliance on forward-looking assumptions that are inherently difficult to validate.

This is especially problematic in medtech, where **innovation cycles are long, uncertain, and shaped by regulatory, clinical and commercial factors**. In this respect, it is important that the Commission's assessment remains grounded in a sufficiently robust and verifiable evidentiary basis, as reflected in Part I.B of the draft Guidelines.

Recommendation:
The final Guidelines should introduce clear limiting principles, objective criteria, and safe harbours to ensure that speculative risks do not outweigh demonstrable efficiencies.

[1] Draft communication from the Commission – Guidelines on the assessment of mergers under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, available here.

Innovation and potential competition in regulated markets (Part II.B.3; Part II.B.4; Part II.B.5; Part II.A.3)

The draft places significant emphasis on future and potential competition. However, **in medtech, the pathway from early-stage innovation to a viable competitive product is complex and highly uncertain**. It involves regulatory approval, clinical evidence generation, reimbursement decisions, manufacturing scale-up, physician adoption and service infrastructure. As a result, early-stage activities cannot automatically be considered credible competitive constraints.

The draft also allows concerns to arise even in the absence of overlap at product or pipeline level, including at the level of R&D organisations (*§175 et seq.*). This creates considerable uncertainty, particularly where innovation efforts are complementary rather than substitutive. In many cases, acquisitions are a necessary mechanism to bring promising technologies to market, especially where smaller innovators lack the required capabilities to scale independently.

In addition, the introduction of loss of investment competition as a standalone theory of harm (*§169 et seq.*) risks being interpreted as creating a presumption that mergers reduce incentives to invest, even where planned investments are maintained. In capital-intensive sectors such as medtech, this does not reflect the reality that integration often enables, rather than restricts, innovation.

Recommendation:
In this context, the final Guidelines should clarify the evidentiary standard and require a credible, evidence-based assessment of likelihood and impact. They should also clearly distinguish between overlapping and complementary innovation efforts and ensure that speculative concerns do not outweigh demonstrable efficiencies and investment synergies.

Ecosystems and connected products (Part II.B.6; Part II.B.9)

The draft introduces an enhanced focus on ecosystems and interconnected products, raising concerns about foreclosure and customer lock-in. While these concerns may be valid in some instances, **in medtech, integration often delivers substantial efficiencies, including improved clinical workflows, enhanced interoperability, reduced operational complexity and more comprehensive service support**.

The current draft does not sufficiently distinguish between harmful foreclosure and beneficial system integration. Greater clarity would therefore be welcome on how the Commission intends to assess integrated solutions, particularly where they lead to measurable improvements in clinical or operational outcomes.

Recommendation:
The Commission should provide clear analytical criteria to differentiate these scenarios, including when integration improves patient outcomes or clinical efficiency.

Switching costs and indicators of market power (Part II.A.2)

The draft identifies switching costs as a potential indicator of market power. In medtech, however, **switching costs are frequently driven by legitimate clinical and operational considerations, including the need for healthcare professional training, continuity of patient care and investments in equipment and infrastructure**. These factors should not be interpreted as evidence of anti-competitive lock-in.

Similarly, the reference to high profit margins as a proxy for market power (*§68 et seq.*) does not adequately reflect the characteristics of the medtech sector. Margin levels are influenced by high R&D costs, complex

regulatory requirements, long development timelines and significant failure risk. Treating margins as an indicator of market power in this context risks penalising innovation and competitive success.

Recommendation:
Against this background, the Guidelines should explicitly recognise that margin analysis is not a reliable indicator of market power in regulated, innovation-driven sectors.

Buyer power and procurement dynamics (Part II.A.4)

While the draft acknowledges the role of buyer power, it does not fully capture its significance in European medtech markets. **Procurement is typically characterised by public tenders, centralised purchasing bodies, framework agreements and increasing consolidation among hospital groups**. These mechanisms confer significant bargaining power on purchasers and materially constrain suppliers.

Recommendation:
To address these concerns, the Commission should give greater weight to institutional purchaser leverage, particularly in tender-driven markets.

Use of tender evidence (Part I.B.3; Part II.B.2)

Tender data can be a useful source of information but must be interpreted carefully in the medtech context. Tenders are often structured into multiple lots with differing specifications, clinical applications and user requirements. **As a result, participation in the same tender process does not necessarily imply direct head-to-head competition**.

Moreover, outcomes are influenced by a range of non-price factors, including clinical considerations, compatibility with existing systems and service support. A purely mechanical interpretation of bidding overlap therefore risks overstating competitive proximity.

Recommendation:
In this context, the Commission should ensure that tender evidence is assessed in its full operational and clinical context.

Efficiencies, time horizons and evidence (Part II.C.1; Part II.C.2; Part II.C.3)

Although the draft recognises that efficiencies may materialise over longer timeframes (*§§306, 328*), the analysis appears to remain anchored in relatively short time horizons. In medtech, **innovation cycles typically span five to ten years, and many benefits, such as improved diagnostics, better treatment options and enhanced patient safety, emerge gradually and are difficult to quantify**.

A restrictive approach risks systematically under-recognising important efficiencies, particularly those with significant societal and clinical value. This issue is compounded in areas such as supply chain resilience, where benefits are critical but inherently challenging to measure.

Recommendation:
The final Guidelines should therefore adopt a more flexible approach to time horizons and accept a broader range of qualitative evidence, including clinical outcomes and resilience considerations.

Legal certainty and predictability of enforcement (Part II.B.7; Part I.B)

The draft introduces new concepts, including the entrenchment of a dominant position (*§§252–259*), drawing on recent case practice. However, some of these developments remain subject to judicial review, and their

codification at this stage may create uncertainty for businesses. **Medtech companies operate in a highly regulated environment and require a predictable legal framework to support long-term investment decisions**.

Recommendation:
The final Guidelines should exercise caution in codifying legal concepts that remain subject to judicial clarification.

Conclusion

MedTech Europe supports the Commission's objective of ensuring that EU merger control remains effective in dynamic, innovation-driven markets. However, the current draft Guidelines risk introducing overly expansive and speculative theories of harm, combined with insufficiently defined analytical boundaries. In highly regulated and innovation-intensive sectors such as medical technology, this could lead to increased legal uncertainty, disproportionate scrutiny of pro-competitive transactions, and a potential chilling effect on investment, collaboration and innovation.

The medtech sector relies on long development cycles, complex regulatory pathways and the integration of complementary technologies to deliver meaningful improvements in patient care. Mergers and partnerships are often essential to scale innovation, ensure market access and support resilient healthcare systems in Europe.

Against this background, it is essential that the final Guidelines provide a calibrated and evidence-based framework, ensuring that forward-looking assessments remain grounded in robust analysis and that efficiencies, particularly those related to innovation, resilience and patient outcomes, are appropriately recognised. **Such an approach will help ensure that EU merger control continues to protect competition while also supporting innovation, investment and, ultimately, timely access for patients in Europe to safe, effective and high-quality medical technologies**.

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.

www.medtecheurope.org.

For more information, please contact:

Mirella Kavadaki
Manager Legal & Compliance – Legal Counsel
MedTech Europe
m.kavadaki@medtecheurope.org