

MedTech Europe's Contribution to European Commission Consultation on "Draft Guidelines on Abusive Exclusionary Conduct"

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Introduction

MedTech Europe welcomes the Commission's Draft Guidelines on abusive exclusionary conduct (the "Draft Guidelines").¹ Overall, the Draft Guidelines aim to provide clarity and guidance on how competition rules apply in the context of exclusionary practices, which is essential for fostering innovation and ensuring a fair market environment. However, it is crucial to address the unique characteristics of the medical technologies sector, where rapid technological advancements and evolving consumer needs and business models demand a nuanced approach. Therefore, MedTech Europe would like to provide the medical technologies industry perspective and specificities, by making the following recommendations.

MedTech Europe and the medtech sector

- 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 who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. Its purpose is to make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path.²
- The medtech sector stands apart from other industries, including the pharmaceutical industry. Medtech markets are highly innovative, dynamic, and complex. Companies need to continuously innovate to develop new therapies and diagnostic capabilities to treat and diagnose unmet medical needs, increase the safety and performance of existing technologies, and expand indications to cover ever larger patient populations. Medtech companies operate under a highly constrained – and complex – environment, as they are subject to (i) stringent regulatory requirements,³ (ii) different public healthcare reimbursement schemes across EU Member States, and (iii) EU and national public procurement rules. In a number of EU Member States, companies are also subject to rebate and/or payback schemes requiring them to return excess profits if specific healthcare budgets are exceeded.

¹ Draft Guidelines on the application of Article 102 of the Treaty on the Functioning of the European Union to abusive exclusionary conduct by dominant undertakings ("[Draft Guidelines](https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1911)"), available at https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1911.

² For more details on MedTech Europe and its members, please see MedTech Europe's website available at <https://www.medtecheurope.org/>.

³ In particular, requirements set out in the Medical Device Regulation ("[MDR](#)"), the In Vitro Diagnostic Medical Devices Regulation ("[IVDR](#)"), and in horizontal legislation such as the Artificial Intelligence Act ("[AIA](#)"), and the General Data Protection Regulation ("[GDPR](#)").

- Against this background, MedTech Europe is concerned about the presumption rules and the general move away from the well-established effects-based approach proposed by the Draft Guidelines and the ECJ case law. Careful economic analysis is more necessary than ever to correctly assess market power and restrictive effects in such a highly innovative, dynamic and complex space. Any shortcut, such as in the form of presumptions, risks leading to erroneous conclusions and creating wrong incentives in the market, including underinvestment in technologies and therapies that are life-saving and cost-efficient for public healthcare systems.
- Considering the growing importance of digital products and components in the medical technologies sector, MedTech Europe would welcome guidance on the interaction between Article 102 TFEU and the Digital Market Act, particularly for self-preferencing practices that may be relevant for digital platforms in healthcare.

Dominance

The Draft Guidelines have removed the “safe harbour” threshold previously established by the Commission at 40% market share, and now merely indicate that market shares below 10% exclude the existence of a dominant market position in most cases. MedTech Europe would like to submit that such reduction of the safe harbour threshold appears to be both (i) too conservative and not supported by the ECJ case law and (ii) likely to generate significant legal uncertainty.

Besides, the Draft Guidelines set out a presumption rule for having a dominant position with market shares of 50%+.⁴

However, significant market shares, including 50%+ shares, are not necessarily reflective of dominance in markets, such as medtech markets, where companies need to continuously innovate to remain competitive and are pressured by public reimbursement schemes to be as (price) competitive as possible as well as by (public and private) customers (including buying groups) with countervailing buyer power (often purchasing through tenders) who have the ability to impose their purchasing conditions or switch away to other suppliers and are eager to test new innovative devices. In addition, in a sector characterised by constant development and innovation, market share is often not representative of market strength.

Therefore, regardless of market share, medtech companies are in most instances not capable of behaving to an appreciable extent independent of their competitors, customers or consumers. Additionally, and due to these specificities of the medtech sector, striving to reach high market shares, theoretically up to 100% and always outside of abusive practices, is a key driver and incentive for companies to invest heavily in new technologies and to address new and niche medical needs, in order to achieve a sustainable return on investment.

A presumption of dominance above a certain market share therefore puts an unfair burden and disadvantage on medtech companies who must prove that they do not have a dominant position. In practice, it will likely be quite difficult, if not impossible, for an allegedly dominant company to discharge the burden of proof. There is no clear guidance on the evidentiary burden to prove the absence of dominance, and companies generally do not have access to the same data (*e.g.*, sales, prices, costs, terms from competitors) as the Commission to be able to substantially and precisely counter a presumption of dominance and demonstrate that it does not hold a dominant position. A presumption of dominance impacts the freedom of contract, the right to property and stifles competition, which is the opposite of what competition policy should aim to achieve.

⁴ See Draft Guidelines, para. 26.

Exclusionary conduct

- Conduct departing from competition on the merits:** MedTech Europe is concerned that the Draft Guidelines appear to imply that conduct which has the purpose of strengthening a dominant position would not fall under the notion of “competition on the merits”, even if the conduct is not abusive.⁵ This would be inconsistent with the established case-law.⁶ We suggest rephrasing the sentence in paragraph 49 of the Draft Guidelines to read: “[..], provided however that its purpose is not to strengthen its dominant position *and* abuse it.” This would bring it in line with the case-law cited by the Commission itself.

In any case, Further guidance would be required to help dominant undertakings to assess their own conducts, especially given that the Draft Guidelines do not provide any definition of what “competition on the merits” means.
- Exclusivity rebates:** MedTech Europe is concerned that exclusivity rebates are subject to a presumption of being capable of having exclusionary effects⁷ with no need to conduct price-costs tests as is currently the approach and remains the case for other forms of rebates.⁸ There is no reason why exclusivity rebates should be treated differently. They too should be considered not to depart from competition on the merits, unless they result in pricing below cost. Moreover, this would be in line with the position of the European Court of Justice as most recently set out in its *Intel* judgment of 24 October 2024. Taking such a formalistic approach to exclusivity rebates is not appropriate in particular in situations where the framework agreement, including rebate schemes, are set by the contracting authority or customer and not the supplier, as is often the case in the medtech space. The statement that exclusive dealing may be abusive even if it is agreed at the customer's request⁹ ignores the commercial reality in the medtech sector where customers request, and often insist on receiving an offer that includes an exclusivity rebate. The customer will request such offers from competing suppliers and then make its selection. This is competition on the merits, and a presumption that such an offer by a dominant company is an abuse would be wrong. It is for the Commission to demonstrate that a rebate is capable of having an exclusionary effect based on a cost analysis.
- Refusal to supply:** MedTech Europe is concerned that the Draft Guidelines development on refusal to supply result in excessive extension of the essential facilities doctrine, hence stifling innovation on the market. The medtech industry would welcome clarification from the Commission that refusal to supply and refusal to access (which are both addressed in the Draft Guidelines) may raise competition concerns only in exceptional circumstances, with a clear indication of what specific circumstances could trigger such concerns.
- Self-preferencing:** MedTech Europe considers that the Commission's approach on self-preferencing is too formalistic and rigorous, not quite acknowledging that self-preferencing practices are frequent (especially in case of vertical integration) and generally do not raise competition law concerns. The

⁵ See Draft Guidelines, para. 49 (“Such an undertaking may take reasonable and proportionate steps as it deems appropriate to protect its commercial interests, provided however that its purpose is not to strengthen its dominant position or to abuse it.”).

⁶ See, e.g., *United Brands*, Judgment of the Court of 14 February 1978, Case 27/76, para. 189.

⁷ See Draft Guidelines, para. 80.

⁸ See Draft Guidelines, Section 4.3.1.

⁹ See Draft Guidelines, para. 79.

Draft Guidelines should clarify the legal test applicable to such practices, all the more so in view of the limited case law available on the subject.

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- Generally, we believe that a presumption that certain behaviour is capable of having exclusionary effects thereby putting the burden of proof on companies to demonstrate the contrary is overly stringent and risks restricting innovation, the freedom to contract, the right to property, and thereby competition.

Efficiencies

As it operates in an industry that is continuously innovating to improve the performance of the technologies, the medtech industry would benefit from more detailed guidance on the circumstances where objective necessity defences may be accepted. The case law cited to support the examples of objective necessity defences provides limited guidance. For instance, the case-law relating to the *“technical justifications, for example linked to maintaining or improving the performance of the dominant undertaking’s product”*¹⁰ refers to tech cases (i.e., *Google Shopping* (2021) and *Microsoft* (2007)) where the undertakings failed to establish that the technical integration of products they had implemented *“led to superior technical product performance”*. Particularly where the Commission introduces presumptions whereby it places the burden of proof on companies, any guidelines would be incomplete if they would not address in the same amount of detail the complete spectrum of an abuse of dominance analysis. This is essential when – as the Commission puts it – through these Guidelines it seeks to enhance legal certainty and help undertakings to self-assess.¹¹ In that same line, additional guidance on how the relevant market in the context of abuse of dominance is to be defined and considered would be needed, in particular in the context of and in view of the new presumptions.

Conclusive words

In conclusion, MedTech Europe urges the Commission to reconsider several aspects of the Draft Guidelines on abusive exclusionary conduct. The proposed shift from an effects-based approach raises concerns about likely misinterpretations in our rapidly evolving sector, which could hinder investment in critical technologies. Additionally, automatic assumptions about dominance based on market share do not accurately reflect market realities. We also highlight the need for clearer treatment of exclusivity arrangements and greater guidance on objective necessity defences. Addressing these issues is vital for creating a balanced regulatory framework that supports innovation and growth in the medical technologies sector.

¹⁰ See Draft Guidelines, para. 168.

¹¹ See Draft Guidelines, para. 8.