

## EFPIA SUBMISSION IN RESPONSE TO CONSULTATION on the DRAFT ARTICLE 102 GUIDELINES

29 November 2024



The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop, and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. A list of EFPIA member companies and organisations can be found here: <https://efpia.eu/about-us/membership/>

EFPIA welcomes the Commission's efforts to provide updated and modernized guidance to companies, as well as national competition authorities and courts, in the complex space of abusive exclusionary conduct. EFPIA believes that clear guidance capable of enhancing legal certainty and helping undertakings self-assess and tailor their compliance programs and trainings accordingly is essential for a competitive EU single market.

In this context, EFPIA has contributed to the submission made by Baker McKenzie in partnership with Dr. Aleksandra Boutin and Dr. Xavier Boutin (Berkeley Research Group) on behalf of a coalition of multinational manufacturers and industry associations representing different sectors of the economy. We support the views expressed in that submission and we echo the overarching sentiment that the draft guidelines should avoid having an undue chilling effect on procompetitive commercial conduct and, instead, provide clarity as to what is compliant behaviour so that companies carrying out business in Europe can operate efficiently.

In line with the new Commission mandate, it is essential that all policy levers address the structural growth gap between Europe and the rest of the world, recognizing that the EU competes on the global market to attract investment. A competition policy that establishes a robust, fair, and competitive environment that allows companies to compete effectively even when they achieve market shares above certain thresholds is key to ensure that companies continue to look at the EU as a place to invest, create jobs, conduct research and development, launch new innovative products, and grow sustainable businesses. A reversion to form-based presumptions that take precedence over robust economic analysis does not provide companies with sufficient certainty to continue investing and delivering new innovation for the benefit of patients in the EU.

While we are conscious that the draft guidelines are meant to be industry-agnostic, we would like to take this opportunity to bring to the Commission's attention several areas where the proposed approach could have unforeseen consequences for the innovative pharmaceutical industry and the member companies we represent.

**A thoughtful approach to pharmaceutical market definition is critical.** It is important to maintain the presumption of no dominance below the level of 40% in the interest of legal certainty. In the case of pharmaceuticals, market definition and the assessment of market power are particularly complex exercises in highly dynamic markets that ought to reflect a range of regulatory, clinical, and economic factors, including the strong countervailing power of government buyers in a social healthcare environment. Whilst companies compete to innovate on global markets at unprecedented high stake investment levels, the assessment of market definition and dominance for pharmaceutical products occurs on national markets in the EU. To guide businesses in their global compliance efforts, additional certainty is critical to enable companies to self-assess with confidence and to foster business practices that ultimately benefit patients and healthcare services across the EU with new innovation.

**Pharmaceutical companies must contend with a delicate balancing exercise between regulatory obligations and competition law compliance.** The Commission's proposed guidance related to access restrictions is unclear and creates significant uncertainty generally, and for pharmaceutical companies in particular. Pharmaceutical companies have complex regulatory and public service obligations that they must comply with, which often vary between Member States and which are generally expected to become even more onerous in light of the Commission's proposed revisions to the EU General Pharmaceutical Legislation. In line with well-established case law of the Union courts, we believe the draft guidelines should continue to uphold very clearly the key principles that have so far enabled companies to consistently meet patient needs by continuously evolving business models and processes to ensure reliable supply of medicinal products in the EU in line with both the Commission's expectations around supply integrity and the competition law requirements.

Pharmaceutical companies make substantial investments at significant risk to bring each new medicinal product to market with the intention of benefiting as many patients as possible. However, in a heavily regulated environment characterised by increasingly complex country-specific cost-effectiveness and cost containment measures, it is vital that companies retain the freedom to determine the most efficient commercial strategy capable of optimizing patient access to innovative medicines across the EU. Since the development of new medicinal products is inherently intended to meet patient needs, that cannot in itself would be a basis for any potential claim of abuse of dominance with no due regard being given to the specific legitimate commercial, clinical, or regulatory environment. Such an approach would amount to unprecedented interference in a company's freedom to operate in conflict with fundamental principles of human rights and with the Commission's overarching goal of improving Europe's competitiveness.

**Payors in the Member States expect pharmaceutical companies to continuously innovate in how they deliver value to patients and healthcare systems.** The proposed guidance related to multi-product rebates is very general and does not articulate in a clear manner that the potential anticompetitive effects of such rebating practices need to be assessed case-by-case and based on robust economic evidence. More generally, we would argue that such economic analysis is essential to understanding and evaluating 'competition on the merits'. Abandoning an economics-based approach in favour of a form-based approach will undermine the Commission's ability to accurately reflect the complexity of the innovative pharmaceutical industry. The proposed broad-brush approach to presumptions that shortcuts a full-fledged analysis is inappropriate where continuous innovation around multi-product therapies is critical to addressing the most complex disease areas and unmet patient needs, and ignores that medicinal products must meet comprehensive country-specific cost-effectiveness requirements before being allowed onto the market, often in combination with risk-sharing arrangements and robust price regulation.

We look forward to constructively engaging in a discussion with the Commission and other stakeholders in the coming months to collectively ensure that the final version of the guidelines best serves the public interest and contributes to competitiveness and growth in Europe.

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