

POSITION PAPER

of Pharma Deutschland e.V.

on the Call for Evidence for an Evaluation of the Procurement Directives

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Introduction

Pharma Deutschland represents the interests of the pharmaceutical industry both nationally and internationally, engaging with policymakers, authorities, and all relevant stakeholders in the healthcare sector. With around 400 member companies - including both international corporations and small and medium-sized enterprises (SMEs) - Pharma Deutschland is the largest national association in the pharmaceutical and medicinal products sector in Europe.

We welcome the European Commission's initiative to revise the EU Public Procurement Directives. In our statement, we focus on the Directive on Public Procurement (2024/24/EU), assessing it considering the specific requirements of the pharmaceutical industry. As public-law entities, statutory health insurance funds are subject to EU public procurement law. When exceeding certain thresholds, they must conduct EU-wide tenders, particularly for pharmaceutical rebate contracts. Given the large volumes and long contract durations, these thresholds are often exceeded.

While EU procurement law provides a fair framework for procurement procedures itself, the strong emphasis on the lowest price has negative consequences: it threatens long-term supply security. A purely price-driven process, which neglects quality and sustainability aspects, poses the risk of medicine shortages. Therefore, it is urgently necessary to address these shortcomings in a reformed procurement directive.

Given the global challenges in supply chains, Pharma Deutschland calls for an adjustment of EU public procurement law to strengthen the EU's strategic independence and promote competition within the Union. Fair competitive conditions should be created, particularly for SMEs, and sustainable production should be supported.

We consider the following adjustments essential.

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1. Simplification of Public Procurement Procedures

For companies—especially SME and start-ups—structural simplification of procurement procedures is essential to ensure fair access to public tenders. Legal certainty, clear regulations, and user-friendly processes are key to facilitating participation in public contracts.

A central concern is the improvement and harmonization of digital procurement platforms. Technical barriers must be removed, navigation and readability optimized, and standardized identity verification procedures introduced. Additionally, platforms should be consolidated and designed to be more user-friendly to reduce the bureaucratic burden on bidders.

By streamlining procurement processes, not only can competition be strengthened, but innovation can also be fostered, and participation from companies offering sustainable and high-quality solutions can be increased.

2. Promotion of a “Buy European” Rule for Critical Medicines

The increasing globalization of supply chains has highlighted the EU’s dependence on foreign production sites, particularly in the pharmaceutical sector. To achieve strategic independence for essential medicines, award criteria should be more focused on promoting resilience and supply security within the EU.

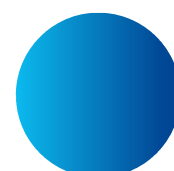
Pharma Deutschland calls for EU public procurement rules to allow preferential treatment of European production sites in specific strategic areas, such as the manufacturing of critical medicines. We propose revising the EU Procurement Directive, particularly Directive 2014/24/EU, so that public contracting authorities can prioritize European production facilities in strategic sectors. This should follow the example of sectoral procurement law (Article 55 of Directive 2014/25/EU) for specific categories of contracts.

Such a regulation would enable targeted support for European manufacturers, particularly in areas of critical public health importance. One potential approach is to focus on active pharmaceutical ingredients (APIs) listed in the European Medicines Agency (EMA) “Union List of Critical Medicines,” which prioritises APIs for EU-wide actions to strengthen their supply chains and minimise the risk of supply disruptions.

3. Revision of the Government Procurement Agreement (GPA)

The GPA ensures equal treatment of market participants from signatory countries. However, in certain cases, greater flexibility is needed to support EU-based producers in strategic sectors. In negotiations with member states, the GPA should be adapted to allow a more flexible application of procurement rules, enabling the EU to prioritize European suppliers in critical areas, such as the production of essential medicines.

4. Integration of Sustainability Criteria as Award Criteria



The long-term economic success and resilience of healthcare systems can only be ensured if ecological transformation is actively integrated into decision-making. Health and sustainability must go hand in hand, as a sole focus on economic efficiency neglects the true framework conditions and ultimately leads to rising costs. Delayed adaptation to future regulatory and environmental requirements will only make the transition more expensive.

To address this, the following measures should be implemented:

- The existing procurement process should be expanded to include sustainability criteria as a weighted factor when evaluating medicines for the same medical indication. Additionally, price adjustments should be accepted when selecting partners.
- A dedicated whitelist should be established for medicines that demonstrably meet predefined sustainability standards, such as a reduced carbon footprint or particularly environmentally friendly production methods. Medicines on this list could be exempt from certain national price regulation instruments, receive a surcharge on fixed prices, or be considered equally economical in discount agreements. The whitelist must be based on clear, verifiable, and objective criteria, ensuring a transparent, non-discriminatory, and future-oriented procurement system.

5. Differentiation of Requirements Based on Risk Management

Localization requirements should be assessed within a comprehensive risk management framework based on geopolitical risks and crisis scenarios. It is necessary to introduce risk management criteria that serve as a basis for determining localization requirements in tenders. The proposed vulnerability analysis model for critical medicines by the Critical Medicines Alliance could serve as a reference.

6. Future-Proofing Award Criteria

Overall, award criteria should be designed flexibly to adapt to future challenges in pharmaceutical supply. Procurement rules must evolve to ensure long-term supply security and resilience in the healthcare sector.

