German Social Insurance
European Representation
50 Rue d'Arlon
1000 Brussels
Belgium

Phone: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparency Register ID:
917393784-81

Deutsche Sozialversicherung
Europavertretung | DSV

Critical Medicines Act: Procurement to strengthen supply

Statement on the Council's General Approach to the Critical Medicines Act, 15 December 2025

On 2 December, the Council adopted its General Approach on the proposed Regulation on critical medicines (Critical Medicines Act, CMA). The aim of the CMA is to strengthen European production and to secure the long-term supply of critical medicines. The German Social Insurance (DSV) expressly supports this objective, as reflected in its position. Laying the foundations for a reliable supply of medicines is an important European task. For the German statutory health insurance funds as the primary payers, this objective is closely linked to ensuring patient care and maintaining an efficient, solidarity-based healthcare system.

From the DSV's perspective, the Council position takes account of different national supply situations and market structures by leaving stockpiling and procurement measures within the competence of the Member States and preserving corresponding scope for action. At the same time, the Council limits the scope of application of the CMA to medicines included in the Union List of Critical Medicines and clarifies that the procurement criteria set out in Article 18 apply exclusively to these medicines, thereby avoiding an expansion of the regulatory framework.

For the DSV, it is crucial that new European requirements are designed in a clear, practicable and financially sustainable manner, that they respect the competences of the Member States, and that they ensure legal certainty and administrative feasibility in practice. This is particularly relevant in the area of public procurement under Article 18 of the proposed Regulation, where statutory health insurance funds in Germany would be especially affected by the new rules. As payers, they conclude rebate contracts with pharmaceutical companies to ensure the supply of medicines. These contracts are an essential instrument for safeguarding the affordability of pharmaceutical care. Interventions through new procurement rules would therefore directly affect established procedures and significantly influence their design, with potential implications for the cost-efficiency of the system and the stable financing of patient care.

We note with concern

- **that, in the Council's view, the additional procurement criteria set out in Article 18 are still to be applied on a mandatory ("shall") rather than a voluntary ("may") basis.** While Recital 24a emphasises that Member States and contracting authorities should be able to decide flexibly which approach is best

suited to the market situation, the current wording of the Article remains anchored in a rigid rule–exception structure.

Should the obligation under Article 18 be maintained in the further legislative process, it is, from our perspective, essential to establish clear and legally sound framework conditions in the trilogue. In particular, it must be ensured that the application of the procurement criteria remains predictable and manageable in practice and does not give rise to new legal uncertainty. A lack of clarity would neither accelerate investment or production decisions nor effectively support the CMA's objective of strengthening security of supply in Europe.

We therefore consider it important

_ **that the Council intends to provide a certain degree of flexibility within the procurement rules, thereby preserving an appropriate margin of discretion for contracting authorities.** Accordingly, it should be sufficient to apply and implement the procurement criteria by selecting one of the known and well-established elements of public procurement procedures. At the same time, already established instruments such as stockpiling obligations or delivery capability clauses may continue to be used. It is also positive that the exemption provisions in Article 18 are to be retained. In narrowly defined cases, such as disproportionate costs, lack of competition or risks to affordability, derogations from the requirements may be applied. This creates necessary and practice-relevant flexibility for the statutory health insurance funds. In doing so, the Council acknowledges that public procurement procedures must take account of both security of supply and cost-efficiency. This flexibility is a key building block and must be preserved in the further legislative process.

We note

_ **that while the Council strengthens legal bindingness and thereby reduces some of the legal uncertainties of the original Commission proposal** by aligning more closely with established public procurement structures, key concepts remain insufficiently precise with regard to concrete regulatory examples. For the legally sound application of Article 18, clear and verifiable requirements are therefore necessary, as non-binding Commission guidance can contribute to clarification only to a limited extent and only at a later stage.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer effective protection against the consequences of major risks of life.