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: Strengthening Security of Supply for Critical Medicines

Statement on the draft report by Tomislav Sokol on the Critical Medicines Act, 11 September 2025

On 18 September 2025, Tomislav Sokol (EPP, Croatia), rapporteur of the European Parliament, presented his draft report on the European Commission's proposal for a regulation on critical medicines (CMA). The aim of the proposal is to strengthen production in Europe and to ensure the long-term supply of these medicines. As already set out in the Opinion of 30 June 2025, the DSV welcomes the objective of strengthening Europe's strategic autonomy and recognising security of supply as a shared European responsibility. At the same time, the DSV stresses that the proposed measures must be precise, feasible and financially sustainable, respect the competences of the Member States, and avoid placing additional burdens on solidarity-based health systems.

We welcome

_ that Tomislav Sokol's report **proposes sanctions** for companies that fail to meet their supply obligations despite receiving public support. This sends a strong signal that public funds must always be linked to enforceable commitments and clear returns.

_ that **national competence for stockpiling strategies** of critical medicines is preserved. Member States are best placed to assess and address the specific needs of their health systems.

_ that **greater transparency on existing stocks** is envisaged. Duplication between national and EU stockpiles must be strictly avoided to ensure efficiency and coherence.

We are concerned

_ about the **extension of the scope to "medicinal products of common interest**." If, as proposed in the report, orphan drugs or novel antimicrobial products, are included in strategic projects and public funding schemes, there is a risk of resource misallocation and a dilution of the CMA's objective. The regulation should therefore remain focused on a narrowly defined set of critical medicinal products

with immediate and critical supply relevance. Orphan drugs already benefit from a privileged status and targeted incentives. Supply shortages in this segment are extremely rare and, for example in Germany, almost never an issue. From the perspective of the DSV, the definition should therefore be sharpened. At present, “critical medicinal products” on the Union list are identified as products of particular importance for public health. However, criteria on supply chain stability are missing. It must therefore be clarified that classification as a critical medicine requires both essential relevance for public health and a critical vulnerability of the supply chain.

_ about the proposal to **introduce mandatory award criteria beyond price** (Article 18 of the draft report). While the DSV acknowledges that additional criteria can in principle support the security of supply of critical medicines, we underline that EU procurement law already enables contracting authorities to include requirements beyond price when awarding contracts. Many Member States, including Germany, already make use of this flexibility. For example, legal requirements require German health insurers to consider medicines manufactured in Europe when concluding rebate contracts. However, mandatory award criteria such as resilience or EU-based production are difficult to measure, restrict the flexibility of tenders, and - combined with mandatory multiple sourcing - reduce the number of companies able to bid at all. This could significantly increase costs for medicines without guaranteeing improvements in supply. Therefore, such criteria should remain optional.

_ about the **proposal to allow price adjustments in public tenders**, particularly for multi-year contracts, in order to provide planning security for industry. According to the draft, contracting authorities would have to commit upfront to minimum volumes and contract durations, while contractors would be allowed to adjust prices during the contract period (e.g. in case of cost increases). Such mechanisms already exist today. In Germany, for instance, pharmaceutical companies may raise their price in line with the consumer price index without incurring an additional rebate. Any further price increases would be difficult to justify and would place unnecessary burdens on health systems. In other pricing mechanisms that involve negotiations between pharmaceutical companies and health insurers, unilateral price adjustment clauses are not acceptable and contradict basic market principles. Moreover, multi-year contracts in Germany usually have limited durations (mostly not exceeding two years) and thus do not entail unmanageable risks. They provide planning security not only for contracting authorities but also for contractors.

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.