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Deutsche Sozialversicherung
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Critical Medicines Act: Practicable procurement rules for secure supply

DSV Statement ahead of the trilogue negotiations, 20 January 2026

With the adoption of its position on the proposal for a Critical Medicines Act (CMA) on 20 January, the European Parliament has taken the next important step in the legislative procedure. The Council had already adopted its General Approach on 2 December 2025 (see DSV statement on the Council's General Approach). With both the Parliament's and the Council's positions now on the table, the interinstitutional negotiations are entering a decisive phase.

The objective 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. For statutory health insurance funds as the main payers, however, security of supply also always means that medicines must remain affordable and that the solidarity-based healthcare system remains financially sustainable. New European requirements must therefore be clear, practicable and financially viable, respect the competences of the Member States, and ensure legal certainty as well as administrative feasibility. In particular in the area of public procurement, statutory health insurance funds in Germany are directly affected by the new rules. In Germany, health insurance funds as payers conclude rebate contracts with pharmaceutical companies. These contracts are a central instrument for ensuring a cost-efficient medicines supply. Any interference through new procurement rules would therefore directly affect established procedures and significantly influence their design.

Against this background, the DSV calls on the Council and the European Parliament to take the following aspects into account in the trilogue:

We consider it important

_ **public contracting authorities retain sufficient leeway when applying the mandatory procurement criteria set out in Article 18 and continue to bear sole responsibility for designing procurement procedures.** In particular, health insurance funds must remain able to flexibly use existing national procurement instruments. This allows them to respond more precisely to the specific supply situation of individual medicines. While the Council follows a comparatively flexible approach in this respect, the position of the European Parliament provides for significantly stricter and less flexible requirements for public procurement under Article 18. This is particularly evident in more binding requirements for multi-winner tenders, in the weighting of non-price award criteria, and in the introduction of fixed

thresholds for “significant” EU production. At the same time, key concepts remain imprecise in both the Parliament’s and the Council’s positions. For the trilogue, it is therefore crucial to establish clear, verifiable and legally certain rules that are also workable in practice. Non-binding Commission guidelines can only contribute to the necessary clarification to a limited extent.

We consider it essential

_ **that the derogations provided for in Article 18 are maintained.** In clearly defined cases – for example where costs would be disproportionate, competition is lacking, or affordability is at risk – it must remain possible to deviate from the procurement requirements. These derogations are indispensable in order to reconcile security of supply with economic efficiency and must be explicitly safeguarded in the trilogue. It is positive that both the Council and the European Parliament recognise the need for such derogations.

We consider it important

_ **that the scope of application of the CMA remains clearly and conclusively limited to the medicines listed on the Union List of Critical Medicines.** We view the extension proposed by the European Parliament to medicines of common interest (MPCI), such as orphan drugs, critically, in particular in connection with the application of the procurement rules under Article 18. Orphan drugs already enjoy a special regulatory status and are supported by specific economic incentives. From the DSV’s perspective, the Council’s position should be followed and an extension of the scope to non-critical medicines should be avoided. Only in this way can the objectives of the CMA be achieved. The CMA should focus on a clearly limited and defined number of medicines with immediate and critical relevance for security of supply. A disproportionate double incentivisation of certain groups of medicines, such as orphan drugs, should therefore be avoided.

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.