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

Tel.: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparency register no.:
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Deutsche Sozialversicherung
Europavertretung | DSV

Feedback from German Social Insurance issued on 25 February 2025

European Commission consultation on a proposal for a regulation on critical medicines (Critical Medicines Act)

I. Preliminary remarks

Ensuring a stable and demand-driven supply of medicines is a shared European challenge. The planned regulation on critical medicines (CMA - Critical Medicines Act) could make an important contribution to increasing the reliability of critical medicine supplies. In order to mutually realise this objective, it is crucial that the planned regulation complements the reform of European pharmaceutical legislation appropriately, incorporates existing national measures and also considers the financial viability of healthcare systems in the EU.

II. Opinion

1 _ Evidence-based and transparent measures

The DSV welcomes the CMA's target of reducing dependence on a small number of manufacturers and non-European production sites. However, supply shortages have multiple causes. Increasing the procurement of products from Europe alone will not guarantee a reliable supply. Monitoring the market and supply situation and analysing what causes the shortages will be crucial here. A comprehensive data overview will be a necessary basis for creating measures to increase supply reliability. These measures must prove to be effective without disproportionately increasing the cost of medicines. Classifying them as "critical medicinal products" must also be based on evidence-based and transparent criteria. Whether a medicinal product continues to fulfil these criteria must be verified on a regular basis.

2 _ Diversification as an industrial policy task

Diversification measures are an industrial policy task. In principle, we should welcome whenever the EU uses its own financial resources to implement programmes to promote locations and support pharmaceutical production. Contributions from statutory health insurance funds must not be misappropriated for this purpose. Promoting diversification in the production of pharmaceuticals, precursors, and excipients, as well as investments in European production capacities must demonstrably contribute to greater supply reliability. Relocating production capacities will only increases the sovereignty of a pharmaceutical supply if it does not result in concentrating it elsewhere. Promoting production sites should aim for the highest economic efficiency criteria in order to maintain efficiency and profitability,

e.g. by taking new production methods into consideration and maximising global competitiveness.

3 _ Efficient public procurement

The procurement and reimbursement of medicinal products are responsibilities of the member states. European public procurement law allows qualitative criteria to be included alongside prices. It should be made clear that aspects such as supply reliability, production location and resilience of the supply chain should also be taken into consideration whenever necessary. Public procurement law must continue to ensure efficient use of contribution funds. In Germany, there already exist legal regulations that oblige health insurance funds to procure specific medicinal products from European production when issuing tenders.

4 _ Implementing stockpiling on a subsidiary basis

In Germany, there are mandatory stockpiling obligations for the medicines tendered by the health insurance funds, which are implemented and monitored together with the pharmaceutical companies based on consumption forecasts. Stockpiling obligations and their subsidiary implementation by healthcare providers should remain possible in the future and be considered a potential solution under the CMA. Additionally, the voluntary EU solidarity mechanism for pharmaceuticals can also be used to redistribute existing stocks that exceed national supply needs to member states affected by shortages. Within the framework of the CMA, the stockpiling of active pharmaceutical ingredients as a strategic EU reserve should be examined. To achieve this, inventories must be recorded digitally and in real time. The approach of making pharmaceutical packaging marketable for multinational distribution or EU-wide distribution by using a QR code is expressly welcomed.

5 _ A sensible addition to pharmaceutical reform

The CMA must be sensibly interlinked with the EU pharmaceutical reform: An EU-wide early warning system could increase transparency and serve as an effective tool for preventing supply shortages. Marketing authorisation holders must be obliged to report impending supply shortages and to draw up plans to avoid such shortages. Significant sanctions for non-compliance with supply obligations must also be envisaged for critical medicinal products.

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.