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Deutsche Sozialversicherung
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Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 ("Critical Medicines Act")

I. Opinion

With the regulation proposal for a Critical Medicines Act (CMA), presented on 11 March, the European Commission aims to ensure the long-term security of supply for critical medicinal products within the European Union (EU) and to strengthen resilience against global crises and dependencies. The German Social Insurance (DSV) welcomes this initiative, as a reliable and affordable supply of medicines is essential not only for the healthcare of the 75 million people covered by statutory health insurance in Germany, but for all citizens across Europe.

The supply of medicines in Europe is therefore a pan-European task and cannot be solved at national level alone. Shared challenges thus require joint action, while also respecting the differing national healthcare realities, established structures, and legal frameworks in the Member States. The DSV therefore supports many of the proposals put forward by the European Commission in the context of the CMA but emphasises that these measures must be designed in a socially balanced, economically sustainable, and practically feasible manner.

In Germany, the statutory health insurance funds, as the main financial contributors to the pharmaceutical supply, bear a special responsibility for ensuring sustainable, affordable, and patient-centred access to medicines. They conclude rebate agreements with pharmaceutical companies, finance the provision of medicines for over 75 million insured persons, and thereby ensure the functioning of a solidarity-based healthcare system in Germany. However, demographic change, a shortage of skilled workers, and above all the steadily rising pharmaceutical expenditure in recent years are placing increasing pressure on social insurance systems across Europe. In Germany's statutory health insurance system alone, spending on medicines now exceeds 50 billion euros per year.

The DSV therefore supports targeted measures to strengthen European competitiveness and to reduce geopolitical dependencies in pharmaceutical production and supply. From the DSV's perspective, however, it is essential that access to and affordability of medicines for patients are given equal priority alongside industrial policy goals such as production and location incentives – both must be addressed together.

Against this background, the DSV believes that the following points must be taken into account in the ongoing discussions on the CMA:

Keep procurement procedures flexible – Ensure cost-effectiveness

Article 18 of the draft regulation provides for mandatory, non-price-related criteria for the procurement of critical medicines, such as stockpiling obligations, diversification through multiple suppliers, supply chain monitoring, or the promotion of production within the EU. EU procurement law already allows public contracting authorities to base procurement decisions not only on price but also on other requirements. Germany has made use of this possibility. For example, there are social law provisions that oblige statutory health insurance funds to procure certain medicines under rebate contracts from European production.

A mandatory inclusion of additional procurement criteria, such as those aimed at promoting supply security or production locations, may lead to higher costs, as these criteria often do not align with the lowest price offer. Suppliers who meet these additional requirements often face higher production costs, for example due to production site restrictions within the EU, extensive stockpiling obligations, or increased transparency requirements along the supply chain. In addition, the changed framework conditions could lead to fewer suppliers participating in the competition, as some manufacturers may not be able or willing to meet the additional requirements. This would also reduce price competition and could result in significant additional expenditure for statutory health insurance.

The DSV therefore strongly advocates that Member States continue to be granted broad flexibility in awarding pharmaceutical contracts in order to retain the ability to decide, at national level and on a case-by-case basis, how best to ensure the resilience of medicinal supply.

From the DSV's point of view, it is also essential to involve the national pricing and reimbursement authorities at an early stage in the development and assessment of national programmes for promoting sustainability and resilience in public procurement procedures pursuant to Article 19. These programmes have an impact on the availability, pricing and reimbursement of critical medicines and therefore directly affect the negotiating scope and budgetary responsibility of payers.

In order to ensure legal certainty for public contracting authorities and to ensure that support measures are targeted where supply security is actually at risk, the DSV considers it essential that the classification as a critical medicine or medicine of common interest be based on clear, data-based and transparent criteria. To prevent medicines from being wrongly classified as critical and thereby receiving unjustified preferential treatment, for example through public funding measures, the classification should remain limited to a narrowly defined set of medicines that are particularly relevant to the continuity of supply. The DSV therefore calls for a more

precise definition of the term critical medicine in the CMA. For a medicine to be classified as critical, it should be of significant importance to public health and there should be proven vulnerabilities in its supply chain. Only in this way can those medicines be identified that truly require prioritised EU measures.

The DSV therefore calls for

- **the application of additional European procurement criteria to be voluntary ("may" instead of "shall") in order to maintain the necessary flexibility for national procurement bodies,**

- **the definition of "critical medicines" to be limited to those that are both of particular importance to public health and subject to a structurally vulnerable supply due to significant vulnerabilities in the supply chain, ensuring that support measures target medicines where supply security is truly at risk,**

- **terms such as "medicine of common interest" or " significant share of production in the EU" to be clearly, verifiably, and legally defined in order to ensure transparency and legal certainty for public procurers,**

- **the early and binding involvement of national pricing and reimbursement authorities in the design and assessment of national programmes to promote sustainability and resilience in public procurement procedures, to ensure that the implications for availability, pricing, and budget responsibility are appropriately considered.**

Ensure binding transparency and establish sanction mechanisms

Financial support measures under the CMA must be linked to clear obligations, transparent reporting requirements and effective sanction mechanisms to ensure that public funds are used in a targeted manner and contribute directly to the security of medicinal supply.

According to the DSV, it should therefore be explicitly clarified that companies receiving financial support under Articles 15 and 16 are subject to effective sanctions and penalties in the event of non-compliance with their obligations, such as repayment claims for financial support already granted, contractual penalties or exclusion from future funding measures. Compliance with obligations and the imposition of sanctions and penalties in the event of missing results should be carried

out at the level of the Coordination Group for Critical Medicines vis-à-vis the funded companies.

In addition, Article 17 should ensure that information on the financial support of strategic projects is made available to the competent public authorities, in particular the authorities responsible for pricing and reimbursement. Transparency about public financial and other incentives for research, development and production is essential for well-informed price negotiations and reimbursement decisions.

A sustainable security of medicinal supply also requires that relevant information on production capacities, supply chains and funding is collected systematically and made transparently accessible. The information obligations for market operators provided for in Article 29 of the draft regulation are a first step towards achieving this, but they ultimately fall short. Without concrete sanction mechanisms, transparency remains non-binding.

The DSV therefore calls for:

- **the mandatory disclosure of publicly funded support measures to pricing and reimbursement authorities,**
- **access to data on production capacities for public contracting authorities,**
- **the establishment of effective sanctions against funded companies in cases of violations of information obligations (e.g. reimbursement claims or fines) and supply obligations, in order to enforce the necessary transparency in a binding manner.**

Use public funds in a targeted and sustainable manner

The draft regulation includes industrial policy measures, such as the promotion of strategic projects for the establishment, expansion or modernisation of production capacities within the EU. However, measures to support production sites or to strengthen geostrategic resilience are inherently the responsibility of industrial and defence policy, not of solidarity-based healthcare systems. While it is generally to be welcomed when the EU sets up its own programmes to promote critical medicines or coordinates national initiatives, the form, scope and criteria of such support remain vague in the draft regulation.

In addition, in order to present the proposal within the first 100 days of the new Commission, an impact assessment was omitted. The financial implications for EU and national budgets, and thus potentially also for contributors to social insurance systems, remain unclear.

State support for strategic production capacities can make a meaningful contribution to supply security, provided that it is granted transparently, used effectively and linked consistently to verifiable counter-performance. The DSV expressly welcomes the fact that companies receiving financial support for a strategic project should, according to Article 15 of the draft regulation, be obliged to give priority supply to EU Member States. However, in the view of the DSV, such statutory supply obligations remain ineffective as long as they are not enforced through tangible sanctions.

The DSV generally welcomes the establishment of a Coordination Group for Critical Medicines, which is to support the coordination of strategic projects as well as joint procurement and provide recommendations on priority vulnerability assessments. What is essential, however, is that a fair and balanced composition of the group is ensured, in particular through the involvement of national authorities responsible for the procurement, pricing and reimbursement of critical medicines and other medicines of common interest.

The DSV therefore calls for

- **an explicit safeguard ensuring that no contributions from statutory health insurance are misused for industrial policy purposes,**
- **clear outcome obligations for funded companies, in particular with regard to the preferential supply of the EU internal market, and sanctions in case of non-compliance,**
- **the assurance of fair and balanced participation of national authorities in the composition of the Coordination Group for Critical Medicines, in particular those responsible for procurement, pricing and reimbursement.**

Preserve national responsibility for stockpiling

The DSV welcomes the fact that the regulatory competence for stockpiling of medicinal products remains with the Member States. As they are most familiar with the specific needs of their healthcare systems and pharmaceutical procurement generally takes

place at the national level, their authority to impose stockpiling obligations should not be limited at European level but rather strengthened wherever possible.

National stockpiling regulations for medicinal products vary widely across EU Member States. In Germany, pharmaceutical companies are required to stock certain medicines – but only those for which a rebate contract with health insurance funds exists. Compared to other EU countries, these requirements are relatively strict. This regulation was introduced in 2023 through the German Act to Combat and Improve the Supply of Medicines (ALBVVG) and is codified in Section 130a(8) of Book V of the German Social Code (SGB V). It obliges pharmaceutical companies that have entered into a rebate agreement with a health insurance fund to ensure supply by stockpiling enough to cover an average consumption period of six months. By contrast, medicines that are not dispensed under a rebate contract are not subject to a mandatory stockpiling requirement by the manufacturer.

Since national stockpiling measures for medicines can affect the internal market and thereby influence the supply situation in other Member States, the DSV calls for Article 20 to be amended to include a mandatory requirement for timely notification of national stockpiling obligations to other Member States. Early and binding communication would enable the other Member States to adjust their own procurement, storage, and crisis response strategies accordingly.

The DSV therefore calls for

- **the preservation of national stockpiling regulations for critical medicines,**

- **an obligation for early and transparent notification of national stockpiling obligations to the Critical Medicines Coordination Group in order to enable coordination and solidarity at the European level.**

Ensure that joint procurement remains voluntary and purpose-driven

Articles 21 to 24 of the draft regulation provide for voluntary support measures by the Commission for joint procurement. The scope of the Commission's autonomy and responsibility depends on the extent of the mandate granted by the Member States: it may act as a supporter in the preparatory phase, as an agent, or as a representative during the implementation of joint procurement. The DSV recognises the added value of such procedures both in times of crisis and beyond health emergencies, particularly for smaller Member States. However, participation in joint procurement must remain

voluntary, as proposed by the Commission, and must not restrict national competences. Rather, the voluntary nature of joint procurement usefully complements national responsibilities.

The DSV calls for:

- **participation in joint procurement procedures to remain explicitly voluntary.**

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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.