# Position Paper
# of the German Medical Association

On the position of the European Parliament dated 20.01.2026 and the position of the Council of the European Union dated 02.12.2025 on the proposed regulation COM(2025)102 for a Critical Medicines Act

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## Preliminary remarks

In its Position Paper from the 25.04.2025, the German Medical Association welcomed the objectives of the Critical Medicines Act. The approach of encouraging Member States to prioritize and financially support projects to strengthen production of critical medicines in Europe, to apply more differentiated procurement criteria, and to expand the possibilities for voluntary joint procurement is supported. A positive aspect of the Commission's proposal is that Member States continue to regulate the creation of contingency stocks themselves while considering the needs of other Member States.

The Council of the European Union and the European Parliament adopted their positions on 02.12.2025 and 20.01.2026 respectively. This Position Paper refers to these two positions in five selected points.

## Position of the German Medical Association

### 1. Scope of Application: Keeping the focus of the Critical Medicines Act in sight

The European Parliament proposes to expand the definition of "medicines of common interest" to medicinal products for rare diseases (orphan medicines), and to extend the provisions of Chapters III and IV to this group of medicinal products.

This risks significantly diluting the focus of the Critical Medicines Act, which is based on securing the availability of critical medicines. Including non-critical medicines in the rules on the promotion of strategic projects would reduce the resources available for supporting the production of critical medicines.

- ***In the Parliament's definition of "medicines of common interest" in Article 3 (5), the reference to medicinal products for rare diseases is to be removed.***
- ***Additionally, the reference to "medicines of common interest" is also to be removed from Chapters III and IV (Article 5, Article 7, Article 15, Article 16, etc.).***

### 2. Obligations of funding recipients: Ensuring the agreed upon use of public funds

Funds used to promote strategic projects are public funds from Member States (Article 15) or the EU (Article 16). In order to ensure that these funds are used in accordance with the Critical Medicines Act, companies that receive financial support must be subject to appropriate obligations.

- ***The European Parliament is supported in its demand that strategic projects must be subject to transparency requirements, as described in the last sentence of Article 15 (1). Article 16 should be amended to reflect these obligations.***
- ***The responsibility of the recipient to demonstrate that received funds have been used within the EU (Articles 15 (3c) and 16 (2d)) is equally supported.***

According to the Commission proposal, a company which receives funds must "use its very best efforts" to ensure that the critical medicinal product remains available in those Member States where it is being marketed. This vague formulation creates a risk that recipients could circumvent their contractual obligations.

- ***As proposed by the Parliament, the inclusion of "very best efforts" in Article 15 (2) should be removed.***

- ***The Parliament's amendment to Article 15 (2) whereby recipients must ensure "appropriate and continued supply to the Union market" is supported. The relevant wording in Article 16 should be amended accordingly.***

In order to ensure that public funds are used as agreed, the Regulation must provide for the possibility of suspending, revoking, or recovering funding in the event of non-compliance with the conditions, and of imposing sanctions on a company that fails to fulfil its obligations. This could occur, for example, because a company does not supply the agreed quantity of medicinal products or prioritizes deliveries to third countries in breach of the contract.

- ***The Parliament's amendment to Article 15 (3a) and Article 16 (2a) introducing the possibility of suspension, revocation, recovery, and sanctions is supported.***

## 3. Award criteria: Non-price-related criteria should be the norm, but exceptions should be possible in individual cases.

The German Medical Association has supported giving greater consideration to non-price-related criteria in procurement procedures, as well as for tenders that allow the contract to be awarded to more than one bidder. This should become the norm.

At the same time, in justified individual cases, it should be possible to maintain price as the decisive factor if applying non-price criteria would lead to disproportionately high costs. This relationship between rule and exception is described in the Parliament's amendment to Article 18 (5). The formulation by the Commission, on the other hand, would allow Member States to largely disregard criteria relating to the security of supply by making generic references to an underfunded healthcare system.

Both the Parliament and the Council aim to task the Commission with the development of guidelines regarding the application of non-price criteria for Member States. The German Medical Association has also endorsed recommendations to this effect in an earlier statement.

- ***The Parliament's formulation of Article 18 (5) is supported.***
- ***The Parliament's and the Council's positions on Article 18 (5a) and 18 (6) respectively are supported.***

## 4. Contingency Stocks: Solidarity and early notification between Member States instead of centralized management

In order to prevent obligations related to contingency stocks in certain Member States leading to shortages in others, the German Medical Association proposed that Member States should notify each other without delay of the introduction of contingency stock requirements. Similarly, in Article 20(3a) the Council proposes that Member States notify the Critical Medicines Coordination Group of any intention to establish or amend national requirements for contingency stocks.

- ***An obligation to give advance notification of national requirements for contingency stocks, as proposed by the Council in Article 20 (3a), is therefore supported.***

In contrast, the European Parliament aims to establish a real-time digital reporting system for national stockpiles and contingency stocks, as well as the establishment of a mechanism

through which the Commission can redistribute stocks between Member States. In addition, the Parliament supports the establishment of Union Stockpiles for critical medicines.

Such mechanisms would constitute a significant encroachment on national competences. They would deprive a Member State of the ability to best protect its population from shortages. From the perspective of the German Medical Association, Union stockpiles should be limited to disaster scenarios and (imminent) health emergencies. EU law has already laid the groundwork for this. However, the situation is different for shortages in non-crisis scenarios. The medicinal products available and reimbursed by healthcare systems differ from Member State to Member State and there are differences in regularly required quantities and prices. The national contracting authorities best understand the needs of their individual healthcare systems. For this reason, it is reasonable that the responsibility of stockpiling remains with the Member States.

Furthermore, the technical feasibility of the stock monitoring system, as proposed by Parliament, appears questionable.

- ***The measures proposed in Articles 20a to 20h by the Parliament are therefore not supported.***

## 5. Joint procurement must leave the Member States room for negotiation

The German Medical Association supports the efforts of the Commission to establish a clear legal basis for the joint procurement of critical medicines and medicines of common interest and to provide for various procedures that can be applied for this purpose.

From the perspective of the German Medical Association, the voluntary nature of participation in joint procurement is crucial, as set out by the Commission, Parliament, and Council.

The Parliament intends, however, to introduce additional content requirements for contracting parties which include minimum binding quantities, the protection of trade secrets, the duration and renegotiation of contracts, derogation from product information and packaging requirements, and a ban on separate negotiations. These requirements, as stipulated in Articles 21 (6a), 22 (5b), and 23 (5b), are biased in the interest of businesses.

It goes without saying that such clauses may be negotiated where they are justified. As rigid requirements, however, such specifications would significantly limit the negotiating flexibility that Member States need in order to provide the fastest and best possible care for patients and the responsible use of public funds. These requirements would, for example, prevent a Member State from procuring a critical medicinal product from an alternative source which can provide it faster and more reliably.

The possibility for oversight bodies or the public to gain access to important contractual documents should not be restricted in advance by contractual agreement. The existing legal protection of confidential data is sufficient.

- ***The requirements proposed by the Parliament in Articles 21 (6a), 22 (5b) and 23 (5b) should therefore be rejected.***