Summary Comment on the "Critical Medicines Act" regulation proposal

The German association of research-based pharmaceutical companies (vfa) welcomes the political goal of increasing the resilience of pharmaceutical supply chains, reducing unilateral dependencies, and ensuring long-term security of supply in Europe. The vfa notes that different product categories, i.e. Union List of Critical Medicines (ULCM) and medicinal products of common interest (MPCI) should enable targeted political control. The vfa calls on the European Commission to design the measures carefully and to implement them in a practical, innovation-friendly and proportionate manner so that innovation, competitiveness, attractiveness of the location and access to innovative medicinal products are not unintentionally jeopardized.

The following points are particularly important:

Strengthen technological sovereignty by building strategic production capacities

Utilize existing data more efficiently to reduce bureaucratic burden

Significantly limit the collaborative procurement of innovative medicinal products

To strengthen Europe's technological sovereignty, the CMA must promote strategically relevant production and innovation capacities across the entire value chain – regardless of company size. In line with Articles 5, 15 and 16, public funding for strategic projects should follow clear, transparent and practicable criteria, including defined indicators of supply vulnerability. Funding instruments must remain innovation-friendly and aligned with existing EU initiatives. According to Articles 7 to 14, strategic projects should benefit from accelerated, coordinated administrative procedures – without creating additional burdens. Article 12 rightly calls for coherence with environmental and chemical legislation to prevent unintended regulatory obstacles. Intellectual property and business confidentiality must be protected throughout.

In addition, Article 29 introduces new data obligations for MAHs regarding supply and logistics chains. Despite promises of confidentiality and no duplication, the potential bureaucratic burden and risk of trade secret disclosure remain high. These obligations must be strictly limited to existing formats (ESMP or EMVS) and to a single authority. EMVS data should be leveraged to create an EU-wide early warning system, enabling real-time supply transparency and

Charlottenstraße 59
10117 Berlin
Telefon 030 206 04-0
Telefax 030 206 04-222
www.vfa.de

reducing the need for costly central warehousing – without any new reporting duties.

The definitions of MPCI in Article 2 in combination with collaborative procurement instruments of Article 21, 22 and 23 pose considerable risks for research-based pharmaceutical companies in terms of pricing, competition conditions, and market incentives in the EU, which could unintentionally hamper innovation and impede access to innovative medicines in countries such as Germany. These provisions entail significant risks to the attractiveness of the German market (including through an increase in parallel trade) and major risks of misuse of procurement as cost-containment instruments, which would further weaken the competitiveness of the EU. Therefore, collaborative procurement of MPCI must be limited to very few specific situations of high urgency and impact for EU patients and include a voluntary mechanism for the manufacturer's consent to list the product as MPCI. At the same time, it must be ensured that the procurement of MPCI does not extend beyond the Member States that are facing access problems. Thus, collaborative procurement must be limited to Member States with comparable access problems and health systems, where procurement offers real added value compared to national mechanisms that have already been exhausted. To this end, clear criteria for market failure and fully exhausted national processes must be established. Finally, safeguards are needed to ensure the confidentiality of procurement prices while limiting parallel trade to avoid unintended consequences for the German market.

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Charlottenstraße 59
10117 Berlin
Telefon 030 206 04-0
Telefax 030 206 04-222
www.vfa.de