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European Federation of Pharmaceutical Industries and Associations

Position on the Critical Medicines Act

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INTRODUCTION

The Critical Medicines Act (CMA) reflects growing political momentum to address medicine shortages and unequal access across Europe. Its core objectives of strengthening supply chain resilience and ensuring timely, equitable patient access are fully supported by the European research-based pharmaceutical industry.

Our sector is a cornerstone of public health and economic development. It drives high-value employment, scientific excellence and strategic investment across Europe. However, in a rapidly evolving global environment, investment is increasingly drawn to regions offering greater predictability and stronger support for innovation. At the same time, Europe's policy landscape is becoming more fragmented, and this is contributing to the EU's declining share of global biopharmaceutical research and development (R&D).

The CMA must avoid compounding these pressures. As it introduces new regulatory obligations and channels public investment, its implementation must be carefully calibrated to align with existing EU and national legislation, avoid duplication and prevent administrative burdens that could deter investment or delay access to medicines. This includes ensuring coherence with environmental and chemical legislation to prevent unintended barriers to manufacturing.

Rather than adding complexity, the CMA should promote streamlined, risk-based measures that enhance Europe's competitiveness and reinforce long-term supply security, including via strengthened collaboration with trusted international partners.

EFPIA stands ready to work with the EU institutions and all stakeholders to ensure that the CMA delivers on its objectives, while maintaining Europe's leadership in pharmaceutical innovation and manufacturing.

DETAILED RECOMMENDATIONS

Effective supply resilience starts with better risk evaluation

Commission's proposal

The Commission's proposal links the Critical Medicines Act to the vulnerability evaluation set out in the General Pharmaceutical Legislation. The evaluation identifies medicines at risk of supply disruption, and especially those reliant on a single country, a limited number of manufacturers or highly concentrated supply chains. Medicines classified as vulnerable could face a wide range of follow-up measures. These include procurement conditions and eligibility for Strategic Projects under Articles 15-27. In addition, further actions may be recommended by EMA's Executive Steering Group on Shortages (MSSG) and enforced by the Commission under Article 134 of the proposed EU Pharmaceutical Regulation. Such measures could include obligations to increase manufacturing capacity, diversify sources of supply, hold safety stocks or participate in EU joint procurement.

Our assessment

EFPIA supports proactive risk assessment, but cautions that the current vulnerability assessment criteria, as developed by the Commission as part of their pilot exercise, rely too heavily on broad indicators like geographic sourcing or supplier concentration. These do not capture key product-specific factors such as manufacturing complexity, reliance on rare inputs (e.g., plasma, radioisotopes), shelf life or actual shortage history. This is especially problematic for biologics, vaccines and advanced therapies, where diversification is often not feasible. Under the current approach, such products could be misclassified as vulnerable, despite having stable, secure supply chains, simply because they rely on specialised production. Overly simplistic indicators would also wrongly flag medicines sourced from trusted non-EU partners like the UK or Switzerland, undermining international frameworks and diverting attention from real risks.

Misclassification could lead to regulatory overreach and trigger disproportionate obligations or procurement distortions, ultimately reducing patient access by discouraging continued supply of essential medicines. And even when such products were classified as vulnerable, limited technical feasibility means that there are few, if any, viable options to diversify production or sourcing.

Our Recommendations

EFPIA supports an amended definition of 'vulnerability evaluation' in Article 3(7), which ensures that assessments are based on recent shortages, product complexity, specific characteristics and EU international commitments. Equally, requiring the MSSG to consult with marketing authorisation holders (MAHs) is essential to enable proportionate, risk-based measures grounded in real-world evidence and what is feasible. Mitigation actions must remain targeted and aligned with the specific vulnerabilities and characteristics of each product and its manufacture.

Collaborative/joint procurement is no panacea to tackle persistent access issues

Commission's proposal

The Commission's proposal allows joint or collaborative procurement mechanisms to be triggered when a medicinal product is a critical medicine with a supply chain vulnerability or is deemed of 'common interest' (Article 3(5)), particularly where persistent access issues exist across several Member States. These tools are intended to address market fragmentation and disparities in patient access.

Our assessment

EFPIA recognises the need to improve equitable access to innovative medicines across the EU. However, the main barriers are often rooted in systemic differences between Member States, such as pricing and reimbursement (P&R) and health technology assessment (HTA) frameworks, budgetary decisions and national policy priorities. These challenges cannot be resolved through procurement mechanisms alone.

In practice, addressing access barriers requires tailored national-level solutions, including structured dialogue between payers and MAHs. This is especially important in smaller and less affluent Member States, where country-specific engagement is more effective than centralised, one-size-fits-all interventions. If applied too broadly, joint or collaborative procurement risks generating significant unintended consequences, including but not limited to:

- Erosion of national competence for access and pricing decisions, by shifting responsibility and accountability to the EU level without adequate mechanisms for local adaptation.
- Increased procedural complexity and slower delivery, as multi-country coordination often involves divergent timelines, legal frameworks and procurement capacities.
- One-size-fits-all inefficiencies, as joint procurement might not accommodate the diversity of epidemiological needs, health system structures and product lifecycle dynamics across Member States.

Our Recommendations

To avoid unintended consequences, EFPIA recommends tightening the definition of 'medicinal products of common interest' (MPCI) under Article 3(5). The designation should apply only in clearly defined, exceptional cases, where there is verifiable evidence of persistent, unresolved access delays, such as a product remaining unavailable in at least three Member States four years after marketing authorisation. Joint or collaborative procurement must remain a measure of last resort, triggered only once national efforts have been demonstrably exhausted. Its use should be proportionate, evidence-based and compatible with national legal, P&R frameworks. This principle should equally apply to critical medicines with identified supply chain vulnerabilities, where all other risk mitigation tools should be prioritised before considering EU-level procurement (Articles 21-23).

Contingency stock obligations must be proportionate and risk based

Commission's proposal

Contingency stock obligations are placed on companies or supply chain actors to maintain buffer stocks of certain medicines in order to reduce the risk of supply disruptions. This concept is different from stockpiling, which involves reserves held by public health authorities to manage an ongoing or expected crisis. Disproportionate and unharmonised contingency stock requirements pose a serious risk to medicine access to patients in need, particularly when contingency stocks are withheld and similar requirements are enforced simultaneously across multiple countries. In Article 20, the Commission states that national contingency stock requirements must not negatively affect other Member States. Such measures must be proportionate, transparent, and respect solidarity across the EU.

Our assessment

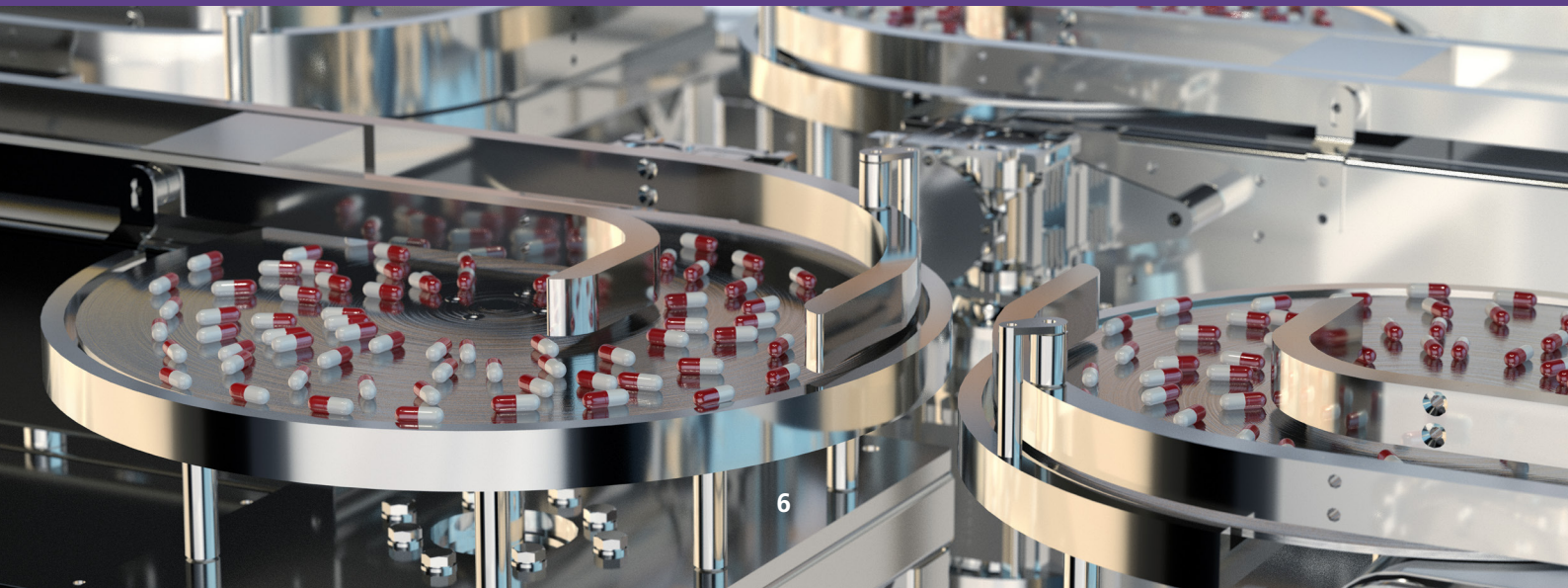
Over the past years, Europe has seen a growing trend of fragmented national contingency stock requirements, as illustrated below.

Marketing authorisation holder contingency stock requirements

Contingency stocks are only one of many strategies to prevent shortages. If poorly designed or applied too broadly, contingency stock requirements could have the opposite effect of what is intended. Overly rigid or excessive stock obligations have the potential to divert resources from actual supply needs, increase waste through unnecessary overproduction and strain manufacturing capacity. In some cases, they might force companies to scale back availability in smaller markets or delay launches altogether, if the logistics of maintaining additional stocks are too complex or costly. Rather than improving access, this leads to inefficiencies, supply bottlenecks and ultimately reduce medicine availability for patients. When such requirements are introduced in an uncoordinated and unharmonised way across different Member States, they risk amplifying these problems, therefore fragmenting supply planning and undermining predictability for manufacturers.

Our Recommendations

- EFPIA recommends improving Article 20 to ensure that contingency stock requirements apply only to truly vulnerable critical medicines, and only when justified by a risk-based supply chain evaluation. Industry involvement is essential to ensure measures are workable and do not disrupt existing supply arrangements.
- Furthermore, to avoid a patchwork of national rules, the EU should establish clear, proportionate Union-level criteria, including limits on stock volumes, duration and flexibility to include unfinished or EU-wide packs. Any EU-level stock initiative should replace and not duplicate national requirements, and be coordinated with Member States.
- Stock obligations must be a last resort, introduced only after other mitigation measures, including those already taken by companies, have been considered. A Delegated Act should define when and how obligations apply, following industry consultation, with annual reviews to ensure proportionality. Stock formats and timelines must reflect manufacturing realities and companies releasing emergency stocks should not face penalties. In line with single market principles, such stocks should not be required to be physically located in the Member State they are intended to serve as long as they are accessible when needed.
- EFPIA also supports strengthening the Solidarity Mechanism for fair, flexible stock redistribution in crises to reduce waste and improve access.
- Finally, the Critical Medicines Coordination Group should act as a technical platform, rather than a central regulator, with regular dialogue to ensure stock policies are feasible and balanced (Articles 25-26).



Rewarding supply chain resilience through a new approach to public procurement

Commission's proposal

The Commission's proposal recognises public procurement as a key tool to improve the availability and security of supply of critical medicines. It encourages Member States to move beyond lowest-price awards and adopt practices that reward supply chain resilience, quality and sustainability. Under Article 18, authorities are expected to consider broader criteria, such as relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. In cases of confirmed vulnerability for critical medicines or when justified by market analysis and public health considerations for MPCIs, targeted procurement conditions may include justified preferences for EU-based suppliers as long as they comply with the Union's international commitments.

Our assessment

EFPIA strongly supports reforming public procurement to better reflect the complex realities of medicine supply and to promote long-term resilience. The industry has long warned that excessive reliance on lowest-price tendering has had damaging effects: it leads to aggressive price erosion, reduces supplier diversity and increases the risk of shortages. This pattern is confirmed by the Commission's own Implementation Report[1] and the European Court of Auditors, which found that in 2021, over 80% of tenders in eight Member States were still awarded to the lowest bidder.

If not corrected, current procurement practices risk undermining rather than enhancing supply resilience. Price-only models incentivise minimum-margin bidding, discourage long-term investment and create brittle supply structures. Contracts awarded to a single low-cost supplier leave no fallback if disruptions arise, which amplifies the risk of shortages. Inflexible specifications or unrealistic lead times can deter participation, especially in smaller or lower-volume markets. Ultimately, such policies threaten continuity of care, limit patient access and work against Europe's broader industrial and health policy objectives.

1. The Commission's Implementation Report recognizes a pattern for the "…preference by contracting authorities to use lowest price as an award criterion, seen as simpler and more objective; best price-quality ratio is used in limited cases, due to fears of risks in compliance audits". "Implementation Report", COM(2021) 245 final (here), 20 May 2021. The subsequent Vogler study for the Commission of 2022 on best practices of medicines procurement also highlighted the significant room for improvement.

Our Recommendations

- EFPIA recommends that Article 18 is improved so that procurement decisions should always be based on a value-based, multi-criteria approach, as reflected in the Most Economically Advantageous Tender (MEAT) principle. This means systematically giving weight to factors such as patient impact and clinical value, environmental sustainability, innovation, supply chain robustness and agility. To reduce vulnerability and avoid single points of failure, multiple-winner tenders should be the default, especially for essential and lower-margin products.
- Where targeted procurement conditions are needed to address a confirmed vulnerability, these should be based on objective and verifiable criteria, developed in close consultation with MAHs, and in full compliance with EU obligations under trade and procurement agreements. In this regard, EFPIA recommends that when assessing the reliability of location of the manufacturing capacity for the purpose of Article 18, trusted, like-minded countries with which the EU has strong regulatory, economic and trade cooperation agreements, such as the UK or Switzerland, shall be considered similar to the EU.
- Furthermore, as the measures in Article 18 are intended to strengthen supply resilience and address vulnerabilities in critical medicine supply chains, EFPIA recommends excluding MPCIs from its scope. By definition, MPCIs do not necessarily suffer from intrinsic supply fragility. Including them risks channelling location-based incentives such as preferential procurement for EU-manufactured products towards medicines that are not vulnerable, which leads to misallocated resources, distorted competition and conflicts with international trade commitments.
- Finally, where procurement intersects with pricing and reimbursement mechanisms, EFPIA urges Member States to apply value-based evaluation models, not simple location-based filters (Articles 18 and 19).

Data requirements must be proportionate, streamlined and aligned with existing systems

Commission's proposal

The Commission's proposal (Article 29) highlights the importance of data collection for supporting the purpose of this Regulation such as the vulnerability evaluation. It allows the Commission to request data from companies and other economic operators in the supply chain.

Our assessment

EFPIA agrees that timely and reliable data is critical for improving visibility and informing risk-based decisions. However, if not properly designed, data requirements result in significant administrative burdens without improving supply oversight. Furthermore, when parallel reporting streams are created, this risks fragmenting information flows, generating inefficiencies and diverting resources away from supply continuity efforts. They can also create inconsistencies between national and EU-level systems and add legal uncertainty for companies operating across borders.

Our Recommendations

EFPIA strongly cautions against introducing new or duplicative reporting obligations where robust systems already exist. In this context, EFPIA recommends that Article 29 explicitly reference existing infrastructures such as the European Medicines Verification System (EMVS), the European Shortages Monitoring Platform (ESMP), and relevant national or centralised product registration databases. Any new reporting requirements must be proportionate, clearly justified and narrowly targeted to address specific, demonstrable information gaps. Moreover, such obligations must be developed in close consultation with impacted stakeholders, including MAHs, to ensure they are both technically and operationally feasible.

Resilient supply requires both strategic EU investment and global collaboration

Commission's proposal

The Commission's proposal recognises the strategic importance of reinforcing pharmaceutical manufacturing capacity within the EU and securing access to critical medicines through resilient, diversified global supply chains. It supports the designation of Strategic Projects and encourages measures to remove investment and production barriers, such as streamlining regulation, accelerating approvals and reducing administrative burdens for R&D and manufacturing (Articles 5-12). In parallel, Article 27 promotes international cooperation to diversify sourcing of critical medicines in the Union.

Our assessment

Europe already leads in pharmaceutical manufacturing, accounting for 64% of global API production when including Switzerland and the UK.[2] In 2022, Europe's pharmaceutical output reached €363 billion, with a €158 billion trade surplus in 2023. These figures reflect the importance (and potential) of maintaining and building on Europe's manufacturing strength.

EFPIA welcomes efforts to boost EU manufacturing and believes that a supportive legislative and regulatory environment is essential to achieving long-term supply security. This includes simplifying procedures, ensuring predictability, and promoting investment in advanced, continuous and green production technologies. The Act's support for Strategic Projects is an important enabler in this context.

However, resilience must not be confused with localisation alone. EFPIA cautions against industrial policy that relies on location-based procurement or protectionist incentives, which risk violating WTO obligations, distorting competition and fragmenting the internal market. Instead, resilience should be defined by the strength and flexibility of supply chains, regardless of geography. Moreoever, industrial strategy should focus where Europe has genuine global advantage.

2. EFPIA survey conducted in April 2021. Number of APIs (biological and chemical) sourced or manufactured per region of origin (irrespective of value/volume). A total of 16 EFPIA member companies submitted their input to the survey referring to in-patent and off-patent medicines

Our Recommendations

- EFPIA recommends amending Article 5 to explicitly include the dedication of critical medicine manufacturing capacity and the deployment of digital supply chain technologies as strategic projects. These elements are essential to improving preparedness through maintaining ongoing production "warm", scalable production and real-time disruption forecasting, thereby enabling a faster and more coordinated response to shortages.
- Resilience cannot be achieved through protectionism. EFPIA strongly supports international cooperation on trade, regulatory convergence and supply diversification. The CMA should provide a concrete framework for structured partnerships with trusted third countries to secure access to essential inputs and mitigate exposure to global supply shocks. Open and diversified trade is a cornerstone of EU pharmaceutical security. EFPIA therefore recommends reinforcing Article 27 to embed international cooperation, particularly with like-minded partners such as Australia, Japan, Korea, Switzerland and the UK, as a strategic pillar of resilient supply chains.

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