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Our position

Critical Medicines Act

Securing resilient and diversified supply chains for continuous access

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Executive summary

The European Commission's proposal for a Regulation on the Critical Medicines Act (CMA) is a vital step toward ensuring the availability and security of critical medicinal products. To further strengthen supply security, diversify supply chains and improve access to critical medicines for patients across Europe, policymakers must promote public-private cooperation, trade facilitation policies, and international partnerships. Specifically, policymakers must:

- Strengthen supply chain resilience through global diversification, not localisation;
- Promote international partnerships, trade facilitation and regulatory convergence;
- Mandate most economically advantageous tender (MEAT) criteria in public procurement and avoid protectionist procurement practices;
- Enable flexible pricing for off-patent medicines to safeguard supply sustainability;
- Ensure that collaborative procurement remains voluntary and is used as a last-resort mechanism without undermining national systems, proportionate to the objective pursued;
- Avoid uncoordinated contingency stock and stockpiling measures that disrupt markets or adding an extra layer of requirements;
- Reduce regulatory burden through harmonisation, digitalisation and regulatory flexibility; and
- Ensure inclusive governance with strong industry involvement.

In this way, the EU can avoid protectionism and create an attractive, stable and predictable market environment for life sciences innovation and manufacturing in Europe.

Introduction

Throughout legislative negotiations on the CMA, policymakers must carefully consider how it can address structural challenges in Europe's medicines supply chain. The act must ensure timely access to critical medicines while also promoting supply security through competitive manufacturing, reduced trade barriers and enhanced international cooperation. Achieving the CMA's objectives also requires strong public-private collaboration between the longstanding major producers of critical medicines in the European market, the Member States and national agencies.

While governments play an important role as facilitators, integrators and providers of infrastructure and emergency resources, it is companies that operate supply chains and maintain direct control over sourcing strategies, inventory management and distribution networks. Given this dynamic, effective coordination between governments and the private sector is key for building resilient supply chains.

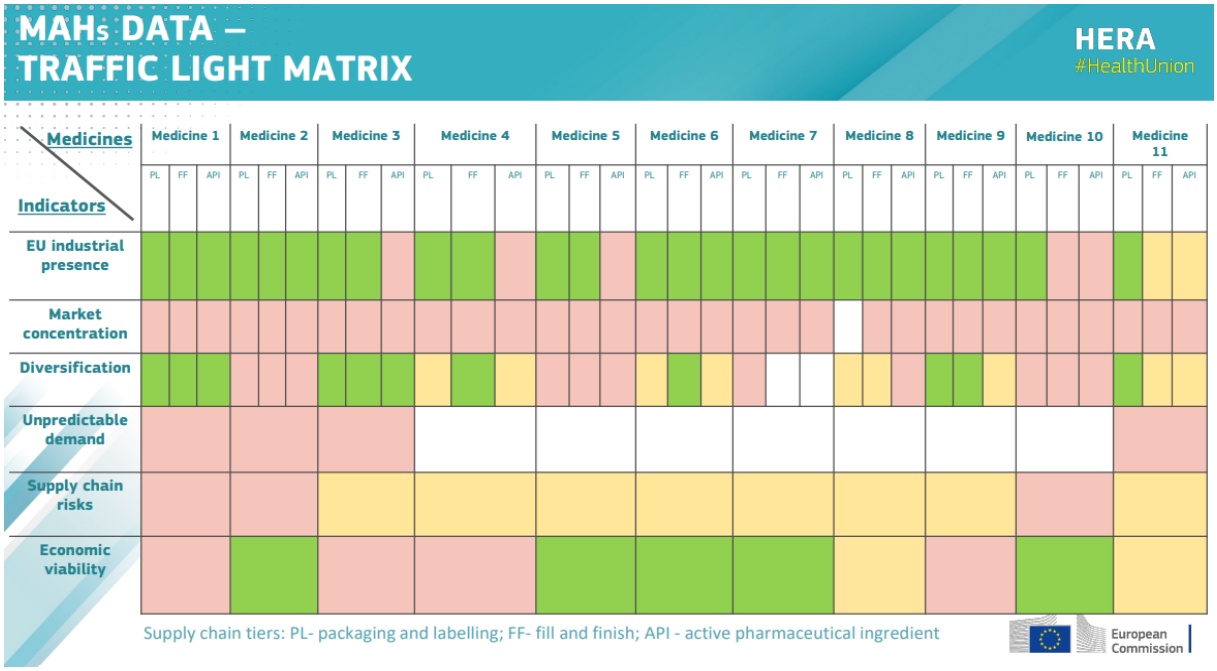
To ensure agility, adaptability and security of supply chains, policy measures must be targeted, evidence-based, proportionate and aligned with international commitments to avoid unintended consequences for supply sustainability and patient access. However, the restrictive localisation strategies included in the proposal risk undermining the resilience of Europe's healthcare systems and the delivery of medicines to patients around the world. Instead, the CMA's measures should reinforce

globally diversified supply chains by bolstering competitiveness, leveraging the EU's track record in industrial policy and implementing systematic market reforms that encourage global partnerships.

The paper below outlines key comments on the proposal, focusing on the most relevant issues to global companies: supply chain resilience and diversification, trade policy, international partnerships, market reforms and governance mechanisms.

Foster resilience of supply chains via diversification rather than concentration

The supply chain vulnerability assessment conducted by DG HERA and DG GROW in 2024 on a subset of critically vulnerable medicines revealed that all 11 molecules studied depend on a single country or manufacturer for over 30% of their supply.[1] This highlights the significant risks linked to market concentration, particularly for multi-sourced, off-patent products. The assessment also evaluated the industrial presence of these molecules. It showed that all 11 have more than 70% of at least one stage of production within the EU, and six molecules have over 70% production at every stage within the EU.[2]



Source: DG HERA, European Commission

Therefore, relying solely on manufacturing presence as an indicator of supply security is misleading. Similarly, assuming that producing medicines outside the EU automatically poses a risk of supply disruption is overly simplistic and inaccurate. An international market approach allows companies to

[1] Health Emergency Preparedness and Response Authority (DG HERA) (2024) *Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines*, *Technical report - public health - European Commission*. Available at: https://health.ec.europa.eu/document/download/67294e68-3a9a-4a73-8c9f-899338bac7f9_en?filename=hera_scv-critical-medicines_1t_assessment_en.pdf

[2] ibid

manage risks by offering more opportunities for adjustments and economic diversifications than strategies confined to any single domestic market. Supply chain risks arise from factors such as concentration, lack of diversification, unpredictable demand and economic pressures, all of which can disrupt supply surges regardless of geographic location. Risk assessment should be made on its own terms, not used as a tool for industrial policy.

Medical supply chains are built on a vast, interconnected network that spans continents to produce and deliver essential medical products to patients in Europe and around the world. Inputs, including various components and equipment, are sourced from hundreds of locations. More than 350 components must be produced, procured from suppliers or local manufacturers, or manufactured in-house – either regionally or globally – before a medicine reaches the local warehouse. No country can make every medicine it requires, and no medicine is manufactured in every country.

Securing robust and diversified global medicines supply chains is essential for Europe to maintain a continuous and stable provision of medical products both domestically and globally, particularly in times of crises. The EU is, by some distance, one of the largest exporters of pharmaceuticals worldwide, and patients around the world rely on the EU for a steady and secure supply of medicines. The CMA should reflect the global, diverse and extensive nature of pharmaceutical supply chains.

Re-localising supply chains can come at a high economic cost. Modelling presented in the recent Organisation for Economic Co-operation and Development (OECD) report on supply chain resilience demonstrates that re-localisation could decrease global trade by more than 18% and global real gross domestic product (GDP) by more than 5%, with no consistent improvements in resilience.[3] GDP stability would decrease in more than half of the economies analysed in the same report. A model-based OECD comparison of two scenarios – a fully interconnected trading regime and a localised regime – showed that some policies aiming to make value chains more domestic could hinder efficiency and would not necessarily offer more stability in the face of shocks.[4]

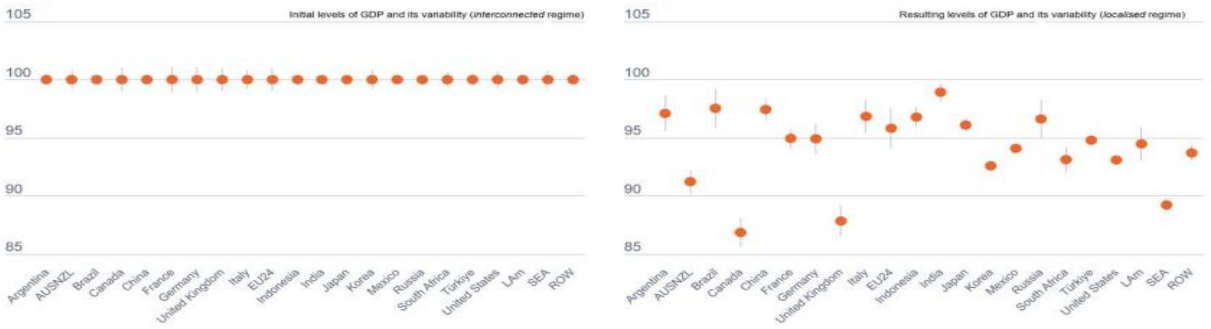
The data show that openness and geographical diversification of input sources and output destinations in global value chains can offer important options for adjusting to disruptions, as well as exposure to shocks from a greater number of sources. The CMA must not focus only on risks related to foreign supply but must address resilience strategies for all types of risks.

[3] The Organisation for Economic Co-operation and Development (OECD) (2024) OECD Supply Chain Resilience Review Navigating Risks. Available at: https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/06/oecd-supply-chain-resilience-review_9930d256/94e3a8ea-en.pdf

[4] ibid

Figure 3.20. Most countries could see GDP declines and more variable output under a "localised" supply chain scenario

Simulated impact on GDP for selected OECD and major other economies of a supply chain localisation scenario



Note: All changes in variables are relative to the level of the interconnected regime base scenario, which is set to equal 100. Orange dots show the base in the given regime relative to the interconnected base and whiskers show average deviations for negative and positive trade cost shocks. SEA=South East Asia; rLAm=other Latin American countries not included individually; ROW=rest of world.
Source: Arriola et al. (2020[3]), "Efficiency and risks in global value chains in the context of COVID-19", https://doi.org/10.1787/3e4b7ecf-en.

Source: OECD

Key policy recommendations

- Recognise that supply risks stem from concentration, not geography.
- Promote global supply chain diversification rather than reshoring or localisation.
- Avoid policies that undermine openness, which could harm supply resilience and global competitiveness.

Support strategic, risk-based approaches to managing vulnerabilities rather than one-size-fits-all manufacturing requirements.

Promote international partnerships via sectoral agreements and international regulatory convergence

The proposed CMA rightly underlines the need to strengthen supply security with diverse supply chains created through international partnerships and collaboration with third countries. Building on lessons learned from the COVID-19 pandemic, it is clear that protectionist and uncoordinated responses to health crises can have a negative impact on critical global supply chains and hinder equitable access to medicines across the globe.

Strengthening global collaboration with the EU's key trading partners is essential to enhancing the resilience of supply chains and reinforcing its strong position in international pharmaceutical trade and related sectors. The EU should maintain its role as a strong advocate for open trade and multilateral cooperation by facilitating resilient, diversified and secure global supply chains. The CMA proposal's reference to strategic partnerships should be reinforced by proactively advancing sectoral agreements for medical goods with key trading partners. These should include clear commitments to open trade and advancing the recognition of equivalent regulatory standards with international partners to ensure uninterrupted patient access to essential medicines and safeguard innovation and collaboration on global challenges. Continued engagement with private and public actors which are

integral to global pharmaceutical supply chains, is vital to ensuring supply security and fostering coordinated, solidarity-based responses to future health emergencies.

Free trade agreements should also include dedicated health security chapters that prioritise the removal of export restrictions, enhanced cooperation during health emergencies and regulatory convergence, which are core elements for strengthening pharmaceutical trade. The ongoing EU-India Free Trade Agreement (FTA) negotiations offer a concrete example of how such priorities can be operationalised. In parallel, advancing trade facilitation policies to simplify and streamline customs and border procedures plays a critical role in maintaining resilient international supply chains. The COVID-19 pandemic demonstrated the importance of measures such as green lanes and digital documentation, which were instrumental in overcoming trade disruptions, reducing delays and ensuring the timely delivery of essential medical goods, including vaccines. To further reinforce global health security, the EU should also recognise the importance of imports from established trade partners and actively promote the export of critical medicines produced in Europe to support access in third countries.

Key policy recommendations

- Pursue sectoral agreements with third countries to reinforce global partnerships and open trade as pillars of supply security.
- Include health security chapters in FTAs, promoting export stability, regulatory alignment and emergency coordination.
- Simplify cross-border trade through measures such as green lanes, digital documentation and mutual recognition of regulatory standards.

Strengthen smart procurement for critical medicines

One of the key elements of the proposed CMA is using public procurement to encourage reliable and diversified supply chains of critical medicines or access to other medicines to improve the availability, supply and production of critical medicines with the EU. According to a European Commission study, 84% of pharmaceutical contracts are awarded based solely on price, which has a direct impact on the sustainability of the market and leads to supply chain consolidation. [9] As the public procurement of medicines is subject to the Public Procurement Directive 24/14/EU, the proposal must shift current procurement practices from price-only award criteria to achieve public health and policy objectives.

Make the application of MEAT award criteria mandatory and avoid localisation

While the application of MEAT criteria is foreseen in the Public Procurement Directive, uptake in the medicines sector remains limited. The widespread use of single-winner, price-only tenders has directly contributed to industrial consolidation, a challenge rightly acknowledged in the CMA proposal. The inclusion of mandatory use of award criteria and procurement requirements beyond price and explicit references to supply security considerations must remain key factors in procurement decisions for off-patent medicines. However, the inclusion of stockholding obligations within this provision risks undermining its intended objective. Fragmented and disproportionate stockpiling requirements create artificial barriers within the internal market, impose inflexible and burdensome costs on manufacturers and ultimately reduce their ability respond effectively to shortages.

Furthermore, policymakers must exercise caution around the introduction of a localisation element, which favours suppliers that manufacture a significant proportion of the medicines within the EU. This approach threatens the sustainability of more agile supplies and misses opportunities for more impactful policies and investments. It includes procurement structures that give preference to manufacturers with local facilities under the assumption that this necessarily translates into improved resilience.

However, this can prove counterproductive due to technical requirements for cleaning manufacturing equipment for product change. Moreover, concentrating the production of multiple medicines within a single production or manufacturing facility may lead to less flexibility. Although such policies may appear to strengthen European-based manufacturing, they can inadvertently increase the risk of supply disruptions rather than reduce it. Localisation may bring adverse effects on competitiveness, quality and compliance when pharmaceutical companies cannot freely select the right location based on a fair assessment.

Instead of focusing on geographic proximity, procurement policies should reward existing supply resilience, including diversification of supply sources and companies' track record of establishing robust supply chains. Relying on a single location, whether in Europe or elsewhere, can represent a greater supply chain risk.

Moreover, such localisation measures conflict with the EU's international trade commitments under the World Trade Organization's Government Procurement Agreement and multiple FTAs, exposing the EU to potential retaliatory trade actions. Additionally, geographic proximity does not necessarily equate to environmental sustainability. Facilities operating with smaller quantities, where feasible, require more frequent cleaning. Moreover, the pharmaceutical supply chain comprises more than ten interconnected steps on average, each demanding different types of facilities—typically distributed across the globe. Instead of restricting sourcing to the EU, procurement policies should embrace diversified supply chains, which include more than one supplier or diversified supply locations. These align with international obligations, enhance supply security and foster strategic partnerships to ensure long-term medicine availability.

Also, a preference towards EU-located manufacturing in public tenders risks running counter to the spirit of the EU's own International Procurement Instrument (IPI), which aims to address third-country restrictions in public procurement markets without resorting to reciprocal protectionism. For example, under the IPI, the EU recently excluded Chinese medical equipment makers from tenders above a certain threshold due to China's refusal to grant reciprocal access to European companies.[5]

Moreover, introducing localisation requirements could undermine the EU pharmaceutical industry's competitiveness by provoking reciprocal measures from global trade partners. The EU's pharmaceutical sector is a significant exporter, with exports reaching €313.4 billion in 2024.[6] The pharmaceutical sector contributed approximately 12.1% to the EU's total extra-EU goods exports, which amounted to €2.584 trillion in 2024. In contrast, imports of pharmaceutical goods totalled

[5] https://www.reuters.com/world/china/eu-backs-curbs-chinese-medical-device-firms-bidding-public-tenders-2025-06-02/

[6] https://ec.europa.eu/eurostat/web/products-eurostat-news/w/ddn-20250414-1

€119.7 billion in 2024. This resulted in a record trade surplus of €194 billion in the pharmaceutical sector, underscoring the EU's strong position in the global pharmaceutical market.[7]

On the other hand, non-price award criteria should, by default, incorporate environmental considerations, including green manufacturing practices and corporate sustainability standards. Embedding such criteria across procurement procedures for off-patent medicines is critical to fostering sustainable industrial development and ensuring fair and equitable competition within the internal market. The discretionary application of environmental criteria, as currently set out in the proposal, risks contributing to a fragmented procurement environment across the EU. Such divergence may result in increased administrative complexity and compliance costs for suppliers operating across multiple Member States, thereby reducing the overall efficiency, predictability and effectiveness of the procurement process.

Finally, greater alignment of procurement criteria across the EU is essential, particularly for globally operating manufacturers. Harmonising these approaches would help develop a more coherent and resilient procurement framework that effectively balances cost efficiency with supply security. By integrating these reforms, the EU can enhance the adaptability and robustness of its medicines procurement system.

Introduce the possibility to adjust pricing, in justified cases

Nine out of ten of Europe's designated critical medicines are off patent, including generics and branded medicines. High volume, low margin off-patent critical medicines are especially impacted by policies that limit companies' ability to adjust prices to accommodate increases in production and regulatory costs and keep up with annual inflation rates. Procurement systems can have a direct impact on supply security and can endanger it by contributing to market consolidation and reducing medicines' economic viability. To secure supply and safeguard the economic viability and continued availability of essential medicines, pricing systems should be flexible enough to allow marketing authorisation holders (MAHs) of critical medicines to adjust prices in response to rising operational costs from new regulatory requirements, labour or inflation.

Make collaborative procurement voluntary

Collaborative procurement has played a key role in ensuring equal access to medicines across Member States in times of emergencies and cross-border health threats. In limited cases, collaborative procurement can help address market failures. However, such mechanisms must not be repurposed, as another cost-containment tool would only increase Europe's widening competitiveness gap and further undermine the pharmaceutical sector's viability in the region. Moreover, because collaborative procurement presents multiple practical and regulatory challenges, it must remain strictly voluntary for both Member States and manufacturers. The CMA should establish a clear, transparent and quantifiable set of criteria to govern when Member States and the European Commission may initiate any collaborative procurement procedures after consultation with the MAH.

The potential challenges include wide disparities in countries' willingness and ability to pay, which often result in protracted and ultimately unsuccessful negotiations. Even with the initial development

[7] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=International_trade_in_medicinal_and_pharmaceutical_products

of the EU Health Technology Assessment (HTA) framework, national HTA processes, economic evaluations and definitions of 'value' continue to vary significantly between countries, regardless of comparable GDP per capita. For example, countries such as Denmark and Germany take divergent approaches to HTA and pricing decisions, despite similar economic standings. A recourse to collaborative procurement between Member States with very different health system, priorities, epidemiological situations, and ability and willingness to pay could delay patient access and be detrimental to health systems.

Patient access barriers stem from a range of complex factors that vary across markets and products, which collaborative procurement would not solve. These include structural and regulatory differences in access pathways, differing national priorities and the evolving nature of advanced therapies targeting small patient populations. As such, collaborative procurement cannot be viewed as a one-size-fits-all solution to address broader issues such as availability, affordability or shortages, particularly outside of emergency contexts.

Collaborative procurement should be used selectively for off-patent medicines, many of which are high volume and low margin. Its focus should be on small-volume products where supply to smaller Member States may not be viable under standard market conditions due to limited economies of scale. In such cases, aggregation of demand may help address volume barriers and improve access. However, corresponding legislation must clearly quantify and justify this rationale when invoking collaborative procurement mechanisms.

There are also important regulatory barriers to collaborative procurement of off-patent products, including divergent national requirements related to marketing authorisation, packaging and country-specific paper leaflets. Addressing these barriers requires a degree of regulatory flexibility – such as enabling the use of multilingual packaging and e-leaflets – to facilitate cross-border supply while maintaining compliance and patient safety.

To ensure consistency and a level playing field, collaborative procurement should be governed by the same principles that apply to national procurement practices. This includes the application of Article 18 of the CMA, which foresees multi-winner models, clear volume allocation and award criteria based on the MEAT and supply security. These safeguards are essential to support competition, reduce the risk of shortages and preserve the sustainability of the supply chain.

In line with the EU principles of subsidiarity and proportionality, any collaborative procurement initiative must remain entirely voluntary for manufacturers, both legally and politically. This means avoiding any form of undue pressure or implied obligation for participation. Moreover, such mechanisms must be underpinned by a clear legal framework with robust safeguards, especially to protect the confidentiality of pricing and contractual terms. Additional, collaborative procurement arrangements – whether undertaken jointly, on behalf of or in the name of Member States – must not conflict with existing national procurement mechanisms or disrupt established market dynamics. The Commission should communicate any intention to launch a collaborative procurement procedure well in advance to all relevant stakeholders to prevent unintended disruptions in supply continuity. Collaborative procurement procedures should be conducted between countries with comparable healthcare systems, capacities and willingness and ability to pay. This would ensure a coherent negotiation process and help safeguard the value of innovation.

Looking ahead, the European Commission and Member States should prioritise policies that strengthen Europe’s investment climate and support a globally competitive pharmaceutical industry.

Long-term access and health security goals are best served by creating an environment that incentivises sustainable private investment and values the contribution of critical medicines to public health outcomes.

Key policy recommendations

- Mandate the use of the MEAT criteria in public procurement, moving away from price-only models.
- Avoid protectionist or localisation-based procurement preferences that contradict EU trade commitments and risk distorting the internal market.
- Encourage procurement models that reward supply resilience, sustainability and supply chain diversification over geographical proximity.
- Ensure environmental and corporate sustainability criteria are applied consistently and avoid fragmentation across Member States.
- Harmonise procurement criteria across the EU to support globally operating manufacturers.
- Ensure collaborative procurement remains voluntary and well targeted.
- For innovative products, ensure that cross-border and collaborative procurement initiatives appropriately recognise the value of innovation and limit their use to cases of genuine market failure, where all other access pathways have failed.

Avoid uncooperative and unilateral measures

For the purpose of clarity, it is important to distinguish the terms 'contingency stock' and 'stockpiling'. The European Commission defines contingency stock as 'an obligation imposed on supply chain actors to establish buffer stocks of certain medicines to mitigate the risk of supply disruption'[8] while stockpiling is 'by a (public) health institution in order to anticipate and manage a specific crisis'[9].

Unilateral and uncoordinated security-of-supply safeguards such as contingency stock or stockpiling are not the answer to avoid out-of-stock situations as they do not address the root causes of shortages. They risk a patchwork of measures that can be counterproductive and impede the flexible allocation of stock to where it is needed most. Moreover, they can have unintended consequences on neighbouring countries and result in unequal access to medicines across the region. Such measures impose additional costs on companies and create artificial increases in demand for critical products, impacting companies' capacity to supply other countries, including other Member States. This can put patient access at risk by inadvertently undermining access to critical medicines in other locations.

Contingency stock, if deemed unavoidable, should apply solely to critical vulnerable medicines products – as identified on the EU's Critical Medicines List and follow-up exercises – with identified supply chain vulnerabilities to keep measures risk based and proportionate. Should the European

[8] https://health.ec.europa.eu/events/info-session-commissions-proposal-critical-medicines-act-2025-04-29_en
[9] ibid

Commission decide to establish EU-level contingency stock requirements, it should coordinate with national authorities to ensure there is no duplication with national equivalent contingency stock and stockpiling arrangements. Contingency stock requirements should only apply for as long as a critical medicine is considered vulnerable from a supply chain perspective. Contingency stock at the MAH level should focus on bulk level to ensure reallocation flexibility.

Stockpiling**,** given its potentially negative impact on patient supply, should be only a last resort when other, more sustainable measures cannot be applied. If imposed, any stockpiling policy must be justified, proportionate, risk based and aligned on the EU level. Stockpiling should be targeted and aligned with distinct risk profiles and actual needs and consider the financial impact of product obsolescence. Any intended stockpiling should consider existing contingency stocks and avoid unwarranted duplication. Stockpiling obligations should focus on the finished goods level to ensure rapid deployment.

Any EU-level security-of-supply requirements such as contingency stock or stockpiling requirements should supersede any similar national requirements to avoid duplication. Any measures should be justified, proportionate and adopted in consultation with the relevant MAHs and other relevant supply stakeholders as well as recognise their shared responsibility. The Commission__ should consider MAHs' self-adopted supply risk and resilience plans before imposing any measures. The CMA should include provisions for multi-language or EU-based packages with harmonised labelling and electronic package leaflets. Existing monitoring tools like the European Medicines Verification System and the European Shortages Monitoring Platform should be interconnected and facilitate EU-level coordination.

Key policy recommendations

- Distinguish between contingency stocks (industry-based buffers) and public stockpiling for crises.
- Limit any unavoidable, contingency stock requirement to vulnerable critical medicines and ensure it is coordinated with national authorities, time limited and flexible (eg at bulk level).
- Ensure public stockpiling is a last resort, risk-based, targeted and non-duplicative of existing measures.
- Ensure EU-level measures override duplicative national requirements and are developed in consultation with MAHs.

Boost shortage prevention via regulatory flexibility

The CMA is a unique opportunity to address current regulatory challenges and create a future-proof regulation that supports timely access to critical medicines via regulatory flexibility and digitalisation. Currently, many medicinal products face regulatory requirements and fees that add cost and complexity to supply chains, such as country-specific packaging and labelling requirements. Regulatory harmonisation of, for example, pack formats, dosage forms and artwork requirements, along with introducing electronic patient leaflets, would significantly reduce manufacturing and supply chain complexity, including financial burdens, ultimately leading to easier and faster patient access.

Likewise, the simplification of shortage reporting and increased collaboration on the forecasting of medicines supply would reduce cost and complexity, facilitating quicker responses and more effective coordination between industry, regulators and healthcare providers. These align with the goals of the EU Competitiveness Compass, which emphasises the need for reduced reporting burdens and greater harmonisation of EU-wide rules to improve conditions for businesses and strengthen Europe's global competitiveness.

Key policy recommendations

- Streamline EU packaging, labelling and reporting requirements to reduce administrative burden and improve supply agility.
- Introduce electronic patient leaflets and harmonised artwork/pack formats.
- Simplify shortage reporting and improve demand forecasting through increased industry-regulator collaboration.
- Support initiatives aligned with the EU Competitiveness Compass to reduce barriers to innovation and supply chain efficiency.

Foster efficient governance

The CMA proposes a Critical Medicines Coordination Group to enhance coordination in implementing the regulation and where appropriate, advise the European Commission on maximising the effectiveness of proposed measures while avoiding unintended consequences for the internal market. The group should include broad stakeholder representation, including industry stakeholders such as MAHs and other actors in the supply chain. Involving industry representatives is critical to ensure that the group can draw upon real-world expertise and lessons learned from all actors working to enhance supply chain resilience and improve patient access to critical medicines. The group should regularly consult the Critical Medicines Alliance initiative – an important step toward identifying and addressing vulnerabilities in the supply of critical medicines – on proposed policy tools and priority actions. Additionally, the Coordination Group should foresee and report on unsustainable market practices that might lead to market consolidation or increased supply chain vulnerability.

Key policy recommendations

- Ensure broad representation in the Critical Medicines Coordination Group, including industry stakeholders such as MAHs.
- Ensure the Critical Medicines Alliance is regularly consulted and plays a role in shaping priority actions.
- Equip governance structures to monitor and address market dynamics that could lead to supply risks or excessive consolidation.

Conclusion

The CMA presents a key opportunity to strengthen the resilience of Europe's medicines supply by promoting globally diversified and flexible supply chains, reinforcing open and rules-based trade in

pharmaceuticals and fostering strategic collaboration with international partners. To be effective, the proposal must avoid restrictive or protectionist measures that risk fragmenting the internal market or disrupting access to medicines across the EU. Instead, it should focus on enabling market-driven solutions, supporting supply diversity, promoting regulatory agility and enhancing the long-term competitiveness of the EU pharmaceutical sector. Achieving these objectives will ensure a stable and accessible medicines ecosystem for patients in Europe and around the world.