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SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Ensuring resilient supply chains for life sciences in Europe

Principles and recommendations for securing medical supplies

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Executive summary

Reliable global life sciences supply chains are fundamental to resilient health systems, encompassing agile global networks that involve multiple components sourced and produced across various sites and countries. Current regulatory approaches often overlook this interconnectedness, leading to fragmented and counterproductive regulations.

To protect these connections and safeguard the resilience of healthcare systems in Europe, the EU and its Member States must:

- Ensure the continued functioning of open global supply chains to deliver patient access.
- Promote collaboration with international partners and all involved stakeholders to improve global supply chain flexibility and resilience.
- Strengthen open trade in life sciences and avoid restrictive or protectionist measures, as they could impact production, supply resilience and availability.

Introduction

Securing robust life sciences supply chains is vital for Europe to maintain a continuous and stable provision of medical products, both domestically and globally, especially during crises. These supply chains encompass the flow of goods and services from product development to distribution and ultimately to the end use by patients, health professionals and healthcare institutions. The supply chain for each medicine is unique, often involving multiple components sourced and produced across various sites and countries, engaging numerous stakeholders.

Globalisation has improved efficiency and availability, increased access to affordable medicine and, importantly, built resilience. However, current regulatory approaches at both the EU and national levels often overlook this interconnectedness, leading to fragmented and sometimes counterproductive regulations and other trade barriers. This position paper provides a comprehensive overview of life sciences supply chains, the challenges faced by the industry and principles for effective government intervention to enhance supply chain security, including global collaboration, regulatory flexibility, competitiveness, and the avoidance of protectionist measures.

Key issues

Life sciences supply chains are global and resilient

Life sciences supply chains are built on a vast, interconnected network that spans continents to produce and deliver essential medical products. Inputs, including various components and equipment, are sourced from hundreds of locations. For example, medicines are produced at scale in multi-product or dedicated facilities by specialised techniques and with expert knowledge. Shipments are transported securely for distribution at all stages of manufacturing (up to 20 steps) and to hospitals and pharmacies in communities around the world. Supply networks are comprised of fit-for-specific-purpose facilities in many countries that all play a role in not only meeting local demand but serving global patient needs. These supply chains are intricate and mutually reliant, requiring seamless

coordination and networking among own sites and contracted facilities to ensure timely delivery of products. Europe and the US both have a fundamental role in the global network of medicines production; for example, the EU is the world's largest exporter of medicines and had a positive trade balance of €158 billion in medicinal and pharmaceutical products in 2023.[1]

Open trade vs protectionism

Strengthening open trade policies and avoiding protectionist measures are vital for maintaining the flow of critical goods and fostering a competitive and innovative industry. In the wake of supply disruptions for certain health products and components during the height of the COVID-19 pandemic, many countries are pursuing production localisation or regionalisation as a means to secure supply availability and increase access. While localisation may seem like a solution for global supply shocks, it does not inherently translate to improved resilience or improved access.

Local production of finished medicinal products is driven by the very limited needs in an individual country and does not equate to autonomy or resilience, as most of the ingredients, machinery, supplies and other production inputs must still be sourced globally. In addition, autonomy and forced localisation do not equal safer or more reliable supply chains.

Furthermore, local production limits the capacity of supply chains to withstand regional shocks, whether caused by sudden spikes in demand due to disease outbreaks or disruptions in supply due to local disasters and even total disruption of the supply chain. The disruption of established global production operations would lose the benefits of economies of scale and could lead to higher production costs. Additionally, relocating existing production might cause additional cleaning efforts, which might not benefit the environment.

No country produces all the medicines it requires, and no medicine is manufactured in every country. There are over 500 molecules on the World Health Organization Essential Medicines List (EML), which lists the basic medicines required for a functioning health system. It is not feasible for each individual country to independently produce this full range of medicines using a variety of specific manufacturing facilities, let alone all other medicines outside of the EML that may offer benefits to health and well-being.

Policies that favour local production for local or regional needs give an advantage to local producers at the expense of global imports. 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 mistaken belief that this necessarily translates to improved resilience. Instead, policies must support the diversified and resilient supply chains targeting those areas where there are identified vulnerabilities (eg limited number of suppliers). Therefore, efficient, most economically advantageous tender (MEAT) procurement criteria to adequately support security of supply without a localisation element and multi-winner tenders should be reflected in public procurement guidelines.

Beyond localisation, it is also important to look at indirect trade barriers. While many countries have zero tariffs on the trade of pharmaceutical products, this is not the case for the goods and raw

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

materials used in the manufacturing of pharmaceutical products. Addressing this is a critical part to lowering the overall cost of manufacturing of medicines in certain geographies.

Finally, the ongoing transformations and increasing demands of the life sciences sector call for a qualified labour force, one capable of working in non-traditional settings under situations of uncertainty and change. Investment in talent and skills creates value: it contributes to better health, builds a strong knowledge base, creates high-quality jobs and enhances manufacturing capacity and exports, which in turn generate more economic value for the region. As a result, policymakers should focus on supporting the research and development (R&D) and manufacturing workforce in acquiring advanced digital and transversal skills, emphasising the need for continuous learning and adaptability. Enhancing EU funding for science, technology, engineering and mathematics (STEM) education, like the Marie Skłodowska-Curie Actions initiative, is also key to build a resilient and innovative workforce. The EU and Member States must retain and attract global STEM talent, including through cross-border mobility with international work permits for highly skilled workforce.

Overall, to better ensure access to medicines and medical products, Member States' and the EU's trade and industrial policies must allow the unhindered movement of medicines and health products across borders, especially in emergencies. Adequate infrastructure, including well-trained personnel, roads, cold chain storage and distribution systems, is necessary to deliver medicines and other essential medical products securely to pharmacies and hospitals. Investments in procuring quality-assured health products must support fair competition and supply security, regardless of production location. While commercial preference for locally produced medical products is not an appropriate tool for supporting supply resiliency, improved access to structural funds and other incentives to increase production capacity in Europe can bolster global manufacturing capacity and contribute to global supply resilience.

Leveraging international partnerships and international regulatory convergence

Despite a challenging geopolitical environment, the transatlantic partnership between the EU and the US remains resilient and strong. This is especially true for pharmaceutical and medical products, which are among the top three goods categories exported by the EU to the US, and vice versa.[2] As major trading partners, the EU and the US should facilitate international trade in medical products and address trade barriers that impact access to medicines globally and hinder the resiliency of supply chains. This would deepen transatlantic trade and economic relations and further strengthen the overall transatlantic partnership. Such an approach should take into account developments in international partners' policies on medical supply chains, which could open the door to a partnership-based efforts to improve the resiliency of those supply chains.
Moreover, global partnership and regulatory collaboration is essential to support existing global supply chain network operations. Mutual Recognition Agreements (MRAs) for pharmaceutical Good Manufacturing Practice (GMP) and their full implementation are crucial tools that can support resource savings for regulators and reduce timelines for supplying imported medicines to patients. Import testing requirements currently impose an average 30-day delay in delivering medicines to patients and reduce shelf life. The EU should consider exploring new MRAs with partners that have appropriate standards, as well as expanding provisions of existing MRAs. Examples include expanding EU-Canada GMP provisions to include active pharmaceutical ingredients (APIs), addressing batch testing requirements between the EU and the UK and potentially expanding the EU-US MRA to include

[2] https://www.consilium.europa.eu/en/infographics/eu-us-trade/

vaccines. In addition, the EU's surprising recent changes in interpretations of MRAs require reestablishing import testing for pharmaceuticals imported to the EU from the US if the biological API is manufactured in a third country, which does not reflect the science nor reality of an enterprise quality management system.

As recently noted in Mario Draghi's strategic report on the future competitiveness of the EU, fostering open global collaboration with the EU's key trading partners to strengthen resilient and open supply chains should be a central objective of any future policies aimed at solidifying and bolstering the EU's international trade position in pharmaceuticals and beyond. This could encompass international cooperation to strengthen supply resilience, notably through the development of strategic partnerships with international partners as well as the optimisation of trade agreements.[3]

Improving supply chain resilience by avoiding uncooperative and unilateral approaches to measures

Measures intended to protect patient access at the national level, such as national stockpiling, can inadvertently undermine access to critical products in other locations. National stockpiling policies impose additional costs on companies and create artificial increases in demand for critical products, impacting companies' capacity to supply other countries, including other EU Member States, contradicting European solidarity.

Recognising the shortfalls of stockpiling is essential, and promoting alternative, structural solutions is key to effectively reducing the risk of shortages in Europe. While a European stockpiling policy may be able to address some specific emergency events, it should not be used to support the regular market supply. Policies should focus on improving the reliability and resilience of the supply chain rather than relying on uncoordinated national stockpiling as the primary strategy for ensuring access for a specific country. Taking a proportionate, risk-based approach to medical supply chains remains critical to the shared goal of preventing or mitigating the shortages of medicinal products. Encouraging diversified manufacturing and supply sources, increasing demand predictability for marketing authorisation holders (MAH), preventing disproportionate penalties for MAHs while excluding wholesalers and/or parallel traders, introducing the possibility of adjusting pricing in duly justified cases and implementing MEAT criteria are more efficient tools to address the real root causes of supply shortages.

Boosting shortage prevention via regulatory flexibility

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, specific stock reporting and additional environmental and sustainability controls. 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 more rapid patient access.

Simplifying and standardising the processes for reporting medicine shortages would also reduce complexity and costs , enabling better management of available information. Establishing clear and straightforward mechanisms for reporting shortages based on a clear understanding of the real demand would facilitate quicker responses and foster more effective coordination between pharmaceutical companies, regulators, and healthcare providers. Utilising platforms like the European

[3] https://commission.europa.eu/document/97e481fd-2dc3-412d-be4c-f152a8232961_en

Medicines Verification System (EMVS) and epidemiological data to predict demand can lead to more timely interventions to prevent or mitigate shortages in patient care. In addition, the added value of the EMVS could be maximised by ensuring full interoperability with the European Shortages Monitoring Platform, allowing for the data to help predict and provide an early warning of potential shortages in order to support mitigation efforts, in addition to ensuring the integrity of the data used for these purposes.

Balancing supply chain transparency requests

Many suppliers face a multitude of supply chain data requirements at both national and European levels, as well as from other governments globally. This often leads to duplicative requests in a variety of formats that expend companies' time and resources to complete and have had limited impact on the root causes of shortages. An example is the requirement included in the EU general pharmaceutical legislation review to have a Shortage Prevention and Mitigation Plan in place using a template provided by the European Medicines Agency (EMA). This template collects information already provided by the MAH through several ways to the relevant European authorities, including EMA itself. This effort, particularly if required for all medicines placed on the market, would overburden the MAH's resources, diverting attention from other more effective mitigation efforts that would be tailored to the needs of the supply chain.

Addressing these redundancies, facilitating the interoperability and connection of the data available and clarifying the purpose of information collection can streamline processes, reduce the burden and ensure data integrity. Scaling up these exercises would necessitate a dedicated internal team, effectively increasing cost of goods and exacerbating viability challenges that have undermined the resilience of supply. This impact can be mitigated by automating the transactional data into one system required for these exercises. This includes interfacing data with Member States on shortage notifications, utilising EMVS data and integrating with the EMA for proactive supply chain risk assessments.

Focusing on critical medicines and market attractiveness

In line with the goals of the Critical Medicines Alliance and as highlighted by European Commission President von der Leyen's statement to the European Parliament in July 2024, a future Critical Medicines Act may represent a pivotal opportunity to strategically address challenges impacting critical products and revitalise the sector. The Act should address the structural challenges of the EU regarding the competitiveness of medicines production and medicine shortages by adopting a multi-dimensional approach that focuses on the overall attractiveness of the market and framework conditions.

The exercise to ensure consistency and draft a European critical medicines list to unify national and European lists is positive. The full harmonisation of an EU critical medicines list and national lists would bring clarity and simplicity to compliance with regulation, allow the life sciences supply chain to prioritise these products and provide an opportunity to discuss with local authorities measures that guarantee the economic viability of such products. However, to ensure that the measures coming as a result of the Critical Medicines Alliance are effective, the list must remain limited and focused, have clear expectations and targeted obligations, and be workable so as not to overburden MAHs and unnecessarily hamper the supply chains of the included products.

Addressing the root causes of critical medicine shortages requires a combination of EU and national measures that consider the economic viability of production. In recent decades, pressure on

healthcare budgets has led EU Member States to introduce pricing and procurement rules aimed solely at reducing the short-term costs of acquiring medicines. This has resulted in the consolidation of supply and an increased risk to supply security.

In procurement, incorporating security of supply as an objective in tender design and including pro-competitive MEAT criteria can incentivise manufacturers to make strategic investments in more robust supply chains. National pricing rules, especially for off-patent medicines should be dynamic and allow adjustments to accommodate increases in production and regulatory costs, environmental stewardship and supply resilience measures, and inflation. For a more successful demand-side policy in the long term, alignment across Member States is essential, particularly regarding criteria that impact the supply chains and manufacturing processes of companies operating globally.

Leveraging the EU's track record in industrial policy, as demonstrated by initiatives like the Chips Act, which prioritised sector incentivisation over increased bureaucratic hurdles, should serve as a guiding principle in any efforts to increase attractiveness and competitiveness of EU manufacturing of critical medicines. Some examples are:

- Identify relevant state aid frameworks the European Commission could implement (such as Important Projects of Common European Interest, Services of General Economic Interest and the General Block Exemption Regulation) , along with funding solutions like EU grants and other investment incentives, to enhance the technology and infrastructure capacity of EU manufacturers (e.g. medicines, APIs, excipients, intermediates and other key components) and foster the development of critical competences (Horizon Europe, regional funds, the Strategic Technologies for Europe Platform, European Investment Bank support).
- Streamline access to various state aid bodies. Industry has called for the establishment of an EU Office of Life Sciences within the Commission, which could ensure alignment and coordination across policy areas that impact the sector. It would oversee and harmonise incentive programmes for medicine production across Member States, ensuring efficient distribution and avoiding duplication of efforts.
- Explore and develop incentives to modernise supply chains, focusing on making medicine production more sustainable and digitised for all stakeholders, regardless of their size or role in the supply chain.
- Proactively identify and implement measures to reduce bureaucratic obstacles that hinder innovation and efficiency. Prioritise optimising existing structures, simplifying administrative processes and reporting requirements, enhancing regulatory clarity and accelerating approval timelines for life sciences R&D and manufacturing projects.

Recommendations

The global supply chain continues to be the best structure for maximising efficient, economical and resilient access to medical products. Recent supply disruptions do not indicate a failure of that structure; rather, market dynamics and systemic root causes have led to supply challenges. A shift away from the global supply chain toward localisation would introduce a new set of issues and leave root causes unaddressed, further exacerbating supply disruptions. The following recommendations target root causes and enhance the functioning of the global supply chain, thus representing the most important actions for fostering a reliable, continuous supply of high-quality medicines.

- **Ensure global supply chain functionality:** Maintain the uninterrupted functioning of interconnected global supply chains to safeguard the resilience of healthcare systems in Europe and patients' access. Life sciences supply chains are agile and built on a vast network that spans continents to produce and deliver essential medical products. Disrupting these networks can lead to inefficiencies and higher production costs. Any measures taken to support resilience of supply chains should be fact-based and follow a thorough identification of vulnerabilities.
- **Promote international collaboration:** Strengthen EU cooperation with key international partners to enhance global supply chain resilience and improve access to medicines. Deepen transatlantic and global trade relationships by addressing trade barriers and fostering regulatory convergence, such as expanding MRAs to reduce delays and streamline supply chain operations. Prioritise issues like batch testing requirements and avoid unnecessary regulatory hurdles. Future policies should focus on global collaboration to ensure open, resilient supply chains.
- **Strengthen open trade:** Encourage open trade in life sciences and avoid restrictive or protectionist measures that could negatively impact production and supply. Policies favouring local production at the expense of global imports risk the sustainability of supply and miss opportunities for more impactful policies and investments. Additionally, it is important to avoid tariffs not only for pharmaceutical products – which many countries already do – but also for the goods and raw materials used in the manufacturing of pharmaceutical products.
- **Build supply chain resilience:** Recognise the shortfalls of national stockpiling and promote alternative, structural solutions to effectively reduce the risk of shortages. A European-wide stockpiling policy should address emergency events but not support the regular supply of the market. Policies should focus on addressing the systemic root causes of shortages and improving the reliability and resilience of the supply chain through diversified manufacturing and supply sources, increasing demand predictability and implementing MEAT criteria.
- **Boost shortage prevention via regulatory flexibility:** Simplify and harmonise regulatory requirements and reporting bureaucracy to reduce costs and complexity. Harmonising pack formats, artwork requirements and dosage forms, along with introducing electronic patient leaflets, can reduce manufacturing complexity and financial burdens. Establishing clear mechanisms for reporting shortages and utilising platforms like the EMVS can lead to more timely interventions.
- **Balance supply chain transparency requests:** Address redundancies and clarify the purpose of information collection to streamline processes including for duplication in shortage reporting. Automating the transactional data required for this exercise is essential, including interfacing data with Member States on shortage notifications, utilising EMVS data on volumes and integrating with the EMA for qualitative supply chain risk assessments.
- **Focus on critical medicines:** Unify national and European lists of critical medicines to ensure consistency, via a targeted, proportionate and risk-based policy interventions. The Critical Medicines Act should address the EU's structural challenges regarding increasing competitiveness of medicines production and reducing shortages by adopting a multi-dimensional approach that focuses on the overall attractiveness of the market. Reform of pricing and procurement rules across the EU is essential for a successful demand-side policy in the long term.

Conclusion

The life sciences sector requires strategic preventive measures by companies to manage its global supply chains effectively. A balanced regulatory approach emphasising proportionality, public-private partnerships, regulatory harmonisation and flexibility will help companies do just that.

Maintaining global supply chain functionality and promoting international collaboration is crucial for resilience. Strengthening open trade and avoiding protectionist measures are vital for sustaining critical goods flow and fostering innovation.

Building supply chain resilience requires structural solutions over national unilateral measures. Simplifying regulations and streamlining information collection would reduce administrative burdens. Unifying national and European lists of critical medicines and reporting would ensure consistency and address production challenges.

The life sciences industry is committed to being collaborative partners in finding long-term solutions without sacrificing patient access. This effort can enhance supply chain efficiency, prevent shortages and ensure the availability of essential medical supplies, benefiting both the life sciences sector and European patients.