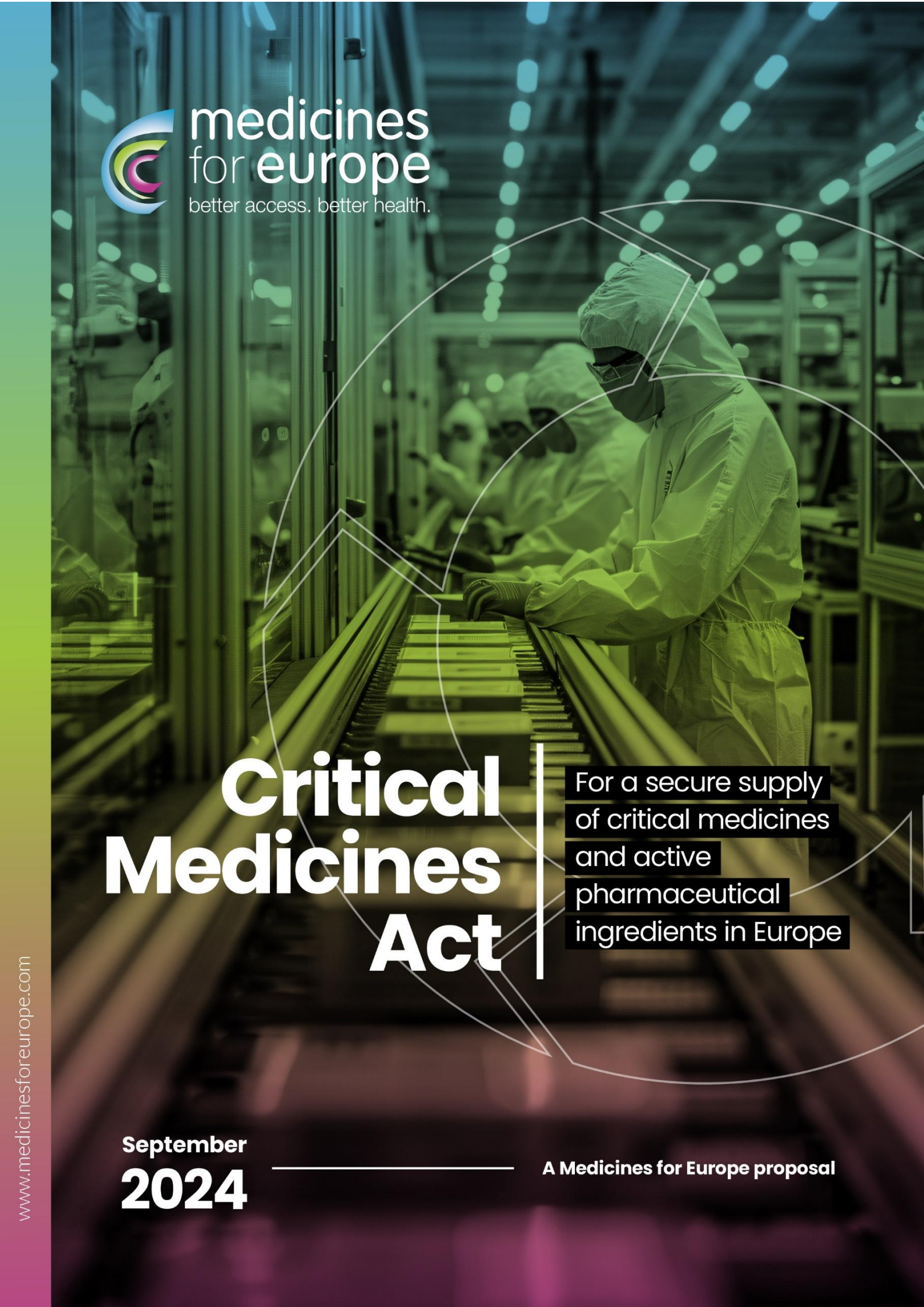

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Critical Medicines Act

For a secure supply of critical medicines and active pharmaceutical ingredients in Europe

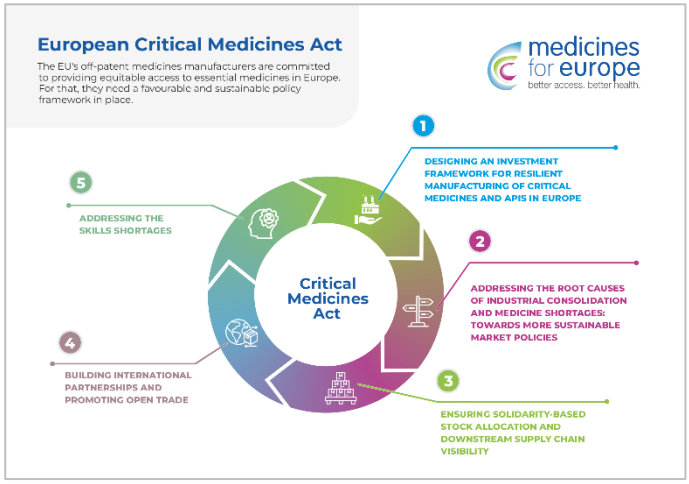
September
2024

A Medicines for Europe proposal

www.medicinesforeurope.com

The Critical Medicines Act should create an ecosystem that promotes healthy competition, rewards sustainable and secure supply chains, and ensure **Open Strategic Autonomy**.

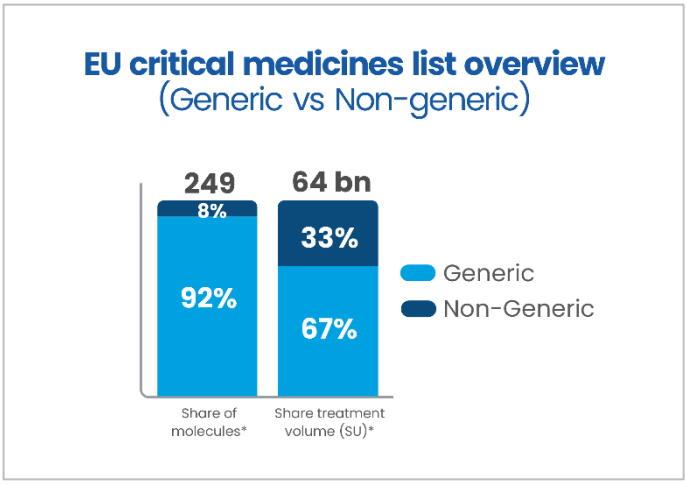
The Act needs to **address the structural challenges** that **disincentivise medicine and API production in Europe**, by encouraging **investment in manufacturing** and more **diversity in supply chains**. This will enable the EU to be ready with a core set of essential medicines during any crisis—whether health-related, in times of war, or in the face of protectionist measures from non-EU countries.



1. Investment in resilient manufacturing

The vulnerability analysis conducted by the European Commission Directorate for Health Emergency Preparedness and Response (DG HERA) and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and multiple other studies[1] have highlighted the **consolidation** of **medicine supply chains** as a **risk to Europe's supply security**. To remedy this, the EU should prioritise **investments in manufacturing of critical medicines and APIs with a**:

⇨ ***Revolution in the definition of innovation of State Aid and Important Projects of Common European Interest (IPCEI) for strategic sectors as recommended in the Draghi Report on EU competitiveness.***



Current State Aid and Important Projects of Common European Interest (IPCEI) **rules restrict funding for (critical) off-patent medicines and API manufacturers**, as they focus on production for new molecules, while 90% of medicines on the critical list are older, well-established molecules. **Expanding the definition of innovation** to include manufacturing processes and investments that support green and digital transitions, as well as security of supply, would enable greater investment in this sector.

[1] Potential measures to facilitate the production of active pharmaceutical ingredients (APIs) (European Parliament)
EU Fine Chemical Commercial KPI, Executive Summary - (European Fine Chemicals Group and IQVIA)
The anatomy of the current antibiotics' shortage (Supply Chain Intelligence Institute Austria)
"Where do our API come from"? (Pro Generika, the German Association of generic and biosimilar medicines)

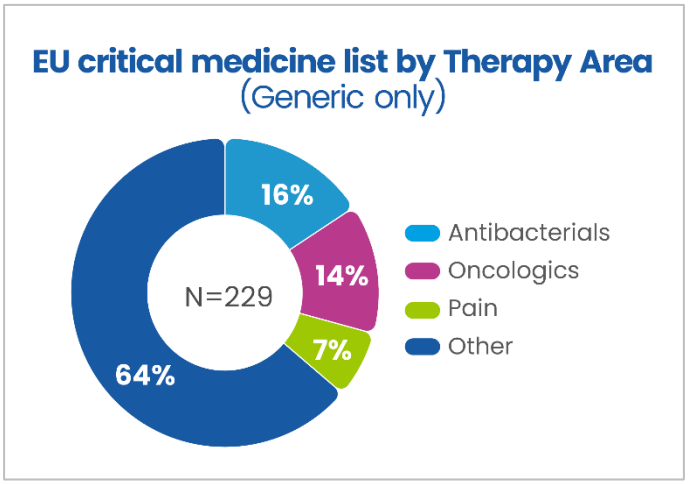
More specifically, the **definition of "first-of-a-kind" facilities** should be updated to reflect the role of **innovative manufacturing** in bolstering supply security. These facilities would incorporate advancements such as automation, continuous manufacturing, and improved environmental performance, while aligning with strict EU environmental and chemical regulations. There should also be a "last production site in Europe" criteria to ensure that the EU has the capability to produce critical medicines and APIs. By enabling the reintroduction of compliant production processes to Europe, these investments would enhance supply chain resilience and sustainability. Such measures would not only address current vulnerabilities in the pharmaceutical supply chain but also ensure adherence to EU environmental standards and support the region's green and digital transitions.

⇨ **Dedicated regional aid for critical medicine and API production**

Unlocking **regional aid** for existing industrial parks with suitable regional infrastructure, which is especially important for API production, could foster the development of sustainable and secure pharmaceutical manufacturing in Europe.

⇨ **Dedicated funds in the Multiannual Financial Framework with health security criteria**

EU funds, such as STEP and EU4Health, should support the production of critical medicines with the **new funding criteria currently being developed by the Critical Medicines Alliance**. The "health security criteria" need to prioritise investments in resilience, innovation of manufacturing processes, and digital and green transitions of critical medicines. As in the Chips Act, the Critical Medicines Act should accept that some funding for more traditional production will be a necessary medicine supply security.



2. Reducing industrial consolidation and medicines shortages

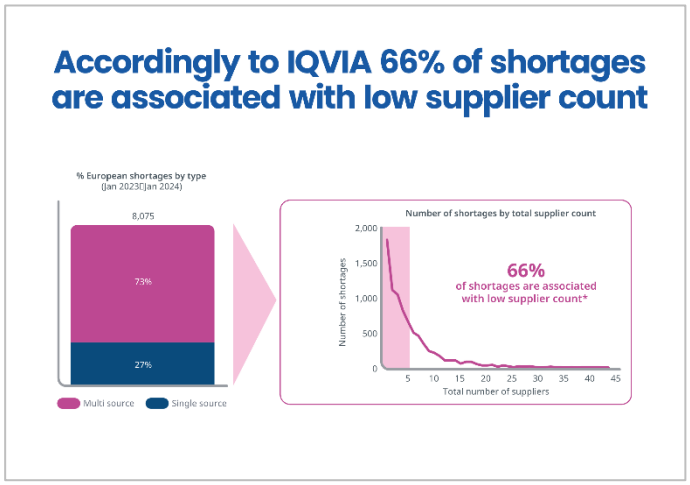
There is a strong body of evidence that the root cause behind critical medicine shortages lies in generic pricing and procurement policies, as evidenced in Commission studies[2] that identify the absence of supply security criteria in market policies as a major risk for the EU. [3]

⇨ **Ambitious medicines procurement reform for health security**

According to IQVIA, tendering accounts for approximately 40% of medicine purchases in Europe, with some countries reporting that 80% to 100% of hospital drug purchases are made through public procurement[4]. Due to

[2] Technopolis Study ''Future-proofing pharmaceutical legislation Study on medicine shortages: final report''
[3] Study on best practices in public procurement of medicines (Gesundheit Österreich GmbH).
[4] https://www.iqvia.com/library/white-papers/from-regulated-prices-to-prices-set-in-tenders?

budgetary pressures, EU Member States have adopted procurement rules narrowly focused on reducing medicine acquisition costs. This approach has driven market consolidation and increased risks to supply security. To address these challenges, **security of supply and non-other price criteria such as sustainability must become a core objective** in tender design, with the application of **Most Economically Advantageous Tender (MEAT) criteria** to incentivise strategic investments in resilient supply chains.



Greater alignment of procurement criteria across the EU is essential, particularly for manufacturers operating globally. The **Critical Medicines Act** should introduce a **dedicated procurement framework** mandating the use of MEAT criteria to prioritise **supply chain security, sustainability, and reliability** alongside cost considerations. By integrating these reforms, the EU can build a more robust and adaptive procurement system that balances **cost efficiency with supply security**, ensuring greater resilience in the medicines market.

⇨ **Smarter Pricing Policies to Balance Competition**

In most EU Member States, **medicine pricing is highly regulated**, and manufacturers do not have the freedom to set their own prices. As a result, during times of high inflation and increasing costs of goods, the security of our medicine supply is at risk. It is essential to adapt regulations to ensure that the **medicine markets can continue to function** and that prices are adjusted in response to rise of costs. For both medicine pricing and security of supply, EU Member States need to reform existing national policies and build on initiatives such as Germany's[5] "Generic Law," Sweden's review of price ceilings, and Portugal's price adjustments linked to inflation to strengthen supply security. Dynamic pricing mechanisms that account for the level of competition should be considered—reducing prices when there are many suppliers, making upward adjustments when suppliers are too few, and increasing the prices of low-cost medicines in line with inflation or other relevant indices to promote market sustainability and resilience.

By using and enforcing the **Transparency Directive[6] as a framework**, the EU could build a more **responsive and resilient pricing system** that balances **cost containment with supply security**. It would enable dynamic **reference pricing adjustments**, ensure **sustainable competition**, and strengthen the **economic viability of essential medicines**. This approach would strengthen **Europe's health security policy** and ensure a more sustainable and secure supply of medicines across the union.

⇨ **Evaluate legislation impacting critical medicine sustainability**

The Critical Medicines Act should also introduce a new specific criterion for European Commission impact assessments of legislation that affects critical medicines production and access to critical medicines – including

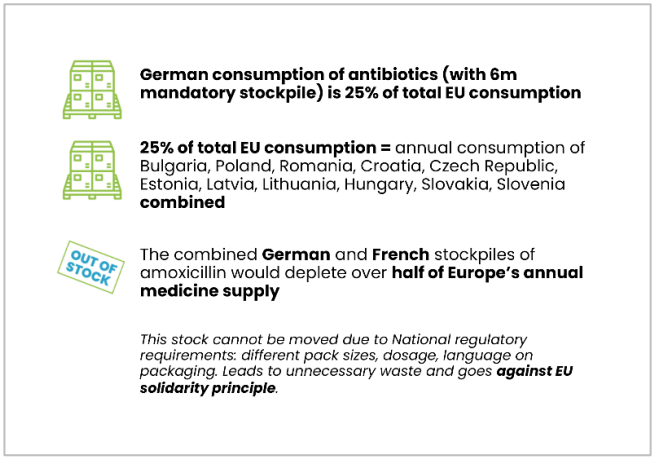
[5] In Germany, the medicines agency (BFARM) monitors drug suppliers and can recommend a change to the pricing system. In Sweden and Portugal, older medicines with low reference prices were subject to a price increase to increase the number of suppliers based on certain conditions.
[6] Transparency Directive (Directive 89/105/EEC)

API production. This would be in line with a "one health" to align the need for environmental protection, with cost-effective, resilient supply chains for access to medicines.

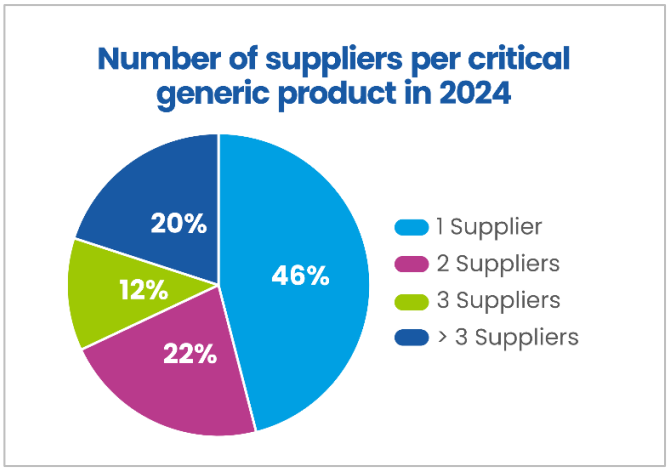
3. Ensuring solidarity-based stock allocation and downstream supply chain visibility

The current trend of excessive and uncoordinated national obligations for MAHs to hold additional safety stocks [7] poses significant risks to the pharmaceutical supply chain, patient access to medicines, and market dynamics. National, and unharmonized safety stock obligations and stockpiling requirements should be replaced with:

- A **European Solidarity Mechanism** that should enable MAHs to efficiently reallocate stocks from one country to another to tackle a shortage.



4. Building international partnerships and promoting open trade



Building on Covid-19 pandemic lessons learned, protectionist and uncoordinated responses to health crises have a negative impact on critical global supply chains and equitable access to medicines around the globe. The European Union should remain a strong advocate for open trade and multilateral cooperation by:

- Ensuring and facilitating robust, resilient and open global supply chains to safeguard patient access to medicines in Europe and beyond.
- Continuing collaboration with key international partners playing crucial role in global medicinal supply chains, as well as accession candidates, on the security of supply and solidarity-based responses to crises

5. Addressing the skills shortages

Under the Pact for Skills, the European Union should address the skills shortage by:

- Developing competence centres to promote the use of sector-specific technologies, providing expertise and skills to the stakeholders, growing a highly skilled workforce in Europe.
- Specific training actions, particularly upskilling and reskilling of low-skilled workers for employment in an industry that is becoming increasingly technical and digitalised.

[7] Medicines for Europe position paper on medicines shortages and national stockpiling requirements: https://www.medicinesforeurope.com/wp-content/uploads/2024/04/240327_Position-paper-stockpiling_FINAL3.pdf