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Critical Medicines Act

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

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A Medicines for Europe position paper

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EXECUTIVE SUMMARY

Medicines for Europe, the European Association representing generic, biosimilar and value added medicines, is engaged in improving EU patient's equitable and timely access to medicines via open strategic autonomy and supply diversification. As 7 out of 10 dispensed medicines in the EU and 9 out of 10 critical medicines are generic medicines, our sector is a vital partner for this the health industrial strategy and Europe's geopolitical security.

Our experience from the COVID-19 pandemic[1] and the Russian invasion of Ukraine[2], as well as growing geopolitical tensions, including possible military scenarios,[3] underline the need for a bold Critical Medicines Act that:

1. **Strengthens industrial competitiveness** through substantial EU funding, flexibilities and fast track procedures in state aid:
    - The EU should allocate €4 billion to medicine manufacturing in the next Multi-Annual Financial Framework to support upgrades for security of supply or environmental improvements to approximately 150 production sites in Europe and could facilitate the "reshoring" of a limited number of molecules of national security interest to the EU
    - Flexible State aid rules, including regional aid, should allow investments in innovative production processes (i.e. capacity increase or modernization), environmental upgrades and digitalisation.
    - As stated in the Draghi report, the definition of innovation in the IPCEI should be expanded to include manufacturing processes for the green and digital transitions and for the security of supply[4].
2. **Integrates supply security** and diversity into **demand-side policies**, considering that off-patent medicine prices are fixed at national level and cannot be increased as any other commodity (the price of bread rose by 45% in the last 9 years while the list prices of the top ten generic medicine suppliers decreased by 8%[5]) – and that up to 84% of national procurement contracts follow price only criteria, through:
    - mandatory non-price criteria in tenders as proposed by the Commission.
    - making the division of tenders into multiple lots the rule where possible.
    - including pricing and reimbursement measures in national programmes supporting security of supply, considering that in approximately 50% of cases, critical medicines are not subject to procurement. This includes for example paediatric antibiotics.

3. **Ensures European solidarity** to tackle shortages **by limiting national stockpiling** to what is proportionate and does not interfere with the secure supply of medicines.

    - The CMA should mandate ex ante notification of national stockpiling mandates to the European Commission with automatic proportionality reviews above threshold levels to ensure consistency with the Internal Market.

    - To ensure that shortages can be addressed quickly, there should be fair remuneration of stockpiling costs, regulatory flexibilities (such as digital leaflets and packaging) and no penalties for using contingency stocks to mitigate shortages in other Member States.

4. **Enables targeted collaborative procurement** where it adds a clear value, while ensuring fair and predictable terms and conditions for manufacturers:

    - Collaborative procurement processes should include clear volume estimates, minimum binding quantities and sufficient lead times to increase demand predictability for suppliers.

    - They should not conflict with national procurement or established market arrangements.

5. **Supports diversification of supply chains** through international strategic partnerships:

    - free trade agreements and other international frameworks should promote the inclusion of health security.

[1] Medicines for Europe Covid-19 lessons learned position paper.
[2] The off-patent industry provided 1200 trucks with medicine to Ukraine after Russia's invasion; see also Statement on the war in Ukraine | Medicines for Europe.
[3] Europe's dangerous medicine dependency is the Archilles heel of its defence strategy' by Health ministers of 11 EU member states published on 09/03/2025 (link).
[4] Draghi report on The future of the EU Competitiveness "Important Projects of Common Interest (IPCEIs) should be expanded to all forms of innovation that could effectively push Europe to the frontier in strategically important sectors and benefit from EU financing" (page 13).
[5] More information on page 16.

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1. Introduction

In recent years, calls for open strategic autonomy in healthcare have grown due to health crises such as the COVID-19 pandemic and rising geopolitical tensions and have been supported by many institutional stakeholders across the EU, including Heads of State and Government in the Versailles declaration[6] and Ministers of Health[7], the European Parliament, as well as by civil society, industry and academia. In response and following the recommendations of the Critical Medicines Alliance and its strategic report[8], the European Commission proposed a Critical Medicines Act in March 2025, within 100 days of the start of its mandate, signalling the Act's high priority.

The proposal rightly recognises the security of supply and availability of critical medicinal products for patients as a strategic objective of the European Union (Article 4) and sets the strengthening of the security of supply and the availability of critical medicinal products (and to an extent other medicinal products) within the EU as the key objective of the Act (Article 1). The main problems that need to be addressed to achieve these aims are dependencies on third countries for medicinal products and their components, especially Active Pharmaceutical Ingredients, and market consolidation.[9] This means that if there is a supply disruption in a third country that a European company relies on, it is unlikely to be able to produce the API or key ingredient itself, and due to market consolidation, there may not be another company in a position to fill the gap on the EU market, leading to shortages.

The proposal has been conceived to complement the revision of the general pharmaceutical legislation to tackle firstly the structural root causes of industrial consolidation and medicine shortages, which lies in the pricing and procurement of these medicines, as evidenced in Commission studies[10] or the study on best practices in the public procurement of medicines.[11] Both studies identify the absence of supply security criteria in market policies as a major risk for the EU. Therefore, making non-price criteria a mandatory part of tender procedures, as proposed in the Act, is a vital step towards prioritising supply security. However, provisions on dividing tenders into lots, integrating supply security criteria also into pricing and reimbursement policies, and addressing national stockpiling obligations need to be strengthened and clarified to ensure uniform application and a functioning market environment.

Additionally, the proposal aims to design a robust investment framework for resilient manufacturing of medicines and APIs in Europe to reduce EU dependency on third-country manufacturing. The Act rightly identifies the need for additional funding from the EU budget and state aid but fails to allocate sufficient funds in the next Multiannual Financial Framework and to introduce sufficient flexibilities in state aid frameworks to make them functional in practice for medicine manufacturing.

[6] Informal meeting of the Heads of State or Government "Versailles Declaration".
7 Non-paper: Improving the security of medicines supply in Europe.
[8] Strategic Report of the Critical Medicines Alliance.
[9] Teva, Teva Generics Health Check, European Critical Medicines Supply Diversity Under Pressure (February 2025).
[10] Technopolis Study ''Future-proofing pharmaceutical legislation Study on medicine shortages: final report''.
[11] Study on best practices in public procurement of medicines (Gesundheit Österreich GmbH).

2. Strengthening industrial competitiveness

In line with the Critical Medicines Alliance strategic report, an **ambitious European investment plan is needed to strengthen production capacities for critical medicines in Europe with an EU-level coordination**.

We welcome the proposed inclusion of strategic projects and the recognition of the need to mobilise additional funding at both EU and national levels. However, we hope that these efforts will not come at the expense of the assessment and financing of other essential projects that also contribute to the security of supply and the competitiveness of the European pharmaceutical sector. A balanced and inclusive approach will be key to ensuring resilient and sustainable medicine production across Europe.

I. European coordination

As recommended by the Critical Medicines Alliance a European investment plan should rely on a combination of an EU funding programme and a state aid regulation allowing support for capacity and strategic projects. Funding solutions should be simple and clear, and we support the idea of a "one-stop-shop" system as proposed by the CMA Strategic Report.

The Commission should support companies and Member States by introducing a streamlined, fast-track approval process with reduced bureaucracy, higher grant thresholds, and flexibility on standard aid ceilings to incentivise investments in production capacity that address supply chain vulnerabilities.

II. Multiannual Financial Framework

The Act only allocates €80 million to support much needed investments in EU medicine manufacturing. This is far too low compared to the €2 billion attributed by India for its industrial strategy, by the United States[12] (well over €1 billion) or the EU Gateway project which provides close to €2 billion investment for pharmaceutical manufacturing in emerging markets.

To encourage private sector investment in medicine manufacturing in Europe, the **EU should allocate €4 billion to medicine manufacturing**. This could support upgrades for security of supply or environmental improvements to approximately 150 production sites in Europe and could facilitate the "reshoring" of a limited number of molecules of national security interest[13] to the EU. It should be delegated to the European Commission to cooperate with industry and with Member States to invest in this strategic sector over the 2026-2030 period. This can be realised by a funding programme dedicated to the production of critical medicines in the upcoming Multi Annual Financial framework, including via the defence and competitiveness funds.

III. Need for new State Aid guidance

The accompanying state aid guidelines to the Act do not reflect the need for EU strategic autonomy. These guidelines are incompatible with the Act's objectives and main priorities of the European Union and should be fully redrafted in consultation with Member States. These rules should allow CAPEX and OPEX investment in

[12] The PILLS bill, currently in Congress, would further allocate considerable tax incentives for the manufacture of generic and biosimilar medicines in the United States. https://www.congress.gov/bill/118th-congress/house-bill/6109/text.
[13] This should be defined by the Commission and the Member States based on the risk assessment scenarios of DG HERA.

production, environmental upgrades for a level playing field, and digitalisation to improve the responsiveness of production to variability in demand. This will support the critical medicines industry in:

- **Mitigating geopolitical risk**: strengthening Europe's pharmaceutical supply chain by enabling the production of upgraded active pharmaceutical ingredients (APIs), finished dosage forms, key starting materials, and critical intermediates within the EU.
- **Investing in innovative production processes**: supporting automation, reducing the use of hazardous materials, and promoting continuous manufacturing. These advancements will lower energy consumption, minimise solvent use (or replace solvents with water), enable low-temperature chemistry for energy savings, and facilitate the adoption of enzymatic chemistry and yield improvement technologies.
- **Boosting water and energy efficiency**: promoting sustainability through investments in solar panels, water capture technologies, and other environmental impact solutions to enhance resilience against climate change and water scarcity while reducing reliance on external resources.
- **Enhancing batch quality control**: implementing innovative industrial technologies to improve the predictability of pharmaceutical production quality.

The guidance also fails to adapt **regional aid** for the development of sustainable and secure pharmaceutical manufacturing in Europe. The European Union should offer Member States the opportunity to implement more flexible regional aid by increasing the share of aid allocated to the production of critical medicines, particularly in historically industrialised regions. This approach would enable companies to strengthen and expand their existing production capabilities, leveraging the availability of a skilled and unskilled workforce and existing industrial infrastructure such as airports, supporting supply chain companies, and ports. Such support would not only enhance production capacity but also ensure the resilience and efficiency of the critical pharmaceutical and API supply chain across Europe.

Furthermore, as also stressed in the recent Draghi report on the future of the EU Competitiveness[14], the definition of innovation in the IPCEI should be expanded to include manufacturing processes for the green and digital transitions and for the security of supply with regional aid limits being more flexible. In addition, the process for receiving funding should be clear and straightforward, with more simplified procedures for the selection and allocation of funds than those currently in place. This will enable EU manufacturers to invest in novel processes and technologies for supply security and adherence to strict EU environmental and chemical regulations. An updated definition of "first-of-a-kind" facilities which contribute to the security of supply of medicines and APIs can be as follows:

'First-of-a-kind facility' means a new or substantially upgraded active pharmaceutical ingredient or finished dosage form (medicine) manufacturing facility, or a facility for the production of other critical components (key starting materials, key intermediates) predominantly used in medicine or active pharmaceutical ingredient manufacturing, which provides innovation with regard to the manufacturing process or final product that is not yet substantively present or committed to be built within the Union, including innovation that concerns improvements in automation, continuous manufacturing, yield improvements or other chemistry or biotechnology processes that contribute to an increase in the level of security, safety or reliability, energy and environmental performance of the production process or site, that would enable the reintroduction into Europe

[14] Draghi report on The future of the EU Competitiveness "Important Projects of Common Interest (IPCEIs) should be expanded to all forms of innovation that could effectively push Europe to the frontier in strategically important sectors and benefit from EU financing" (page 13).

of production that would be compliant with EU chemical, biotechnological or environmental regulations (whereas it may not be compliant in productions outside of Europe), or in the implementation of production processes or other investments on the site that reduce energy, solvents, waste or water resource use in resource intensive chemical or biotechnological processes.'

Recognising that state aid rules are important beyond health security, the European Commission (with the involvement of the Directorates for Health, Health security (HERA) and industry) should issue new *ad hoc* State aid and regional aid guidelines specific to critical medicines and medicinal products of common interest, along with Member States and the concerned manufacturing sectors in relation to the ongoing work on vulnerability assessments.

IV. Coherence with environmental policies

To avoid undermining the objectives of the Critical Medicines Act, it is also essential to ensure strong policy coherence across all Union initiatives that may directly or indirectly impact the supply and availability of critical medicinal products. The European Commission should therefore assess the potential effects on medicine supply chains when preparing legislative proposals, as well as delegated and implementing acts, including those adopted under horizontal Union legislation such as environmental, industrial, or chemical policy.

The recent adoption of the Urban Wastewater Treatment Directive (UWWTD), which introduces an Extended Producer Responsibility (EPR) scheme for pharmaceuticals to finance upgrades and operational costs of thousands of wastewater treatment plants across Europe, shows the risks of insufficient coordination. The Directive imposes a disproportionate and unsustainable cost burden on the generic medicines sector, which supplies over 70% of dispensed medicines in Europe. This threatens the availability, affordability and patient accessibility of essential and critical treatments, particularly those already under ever restrictive pricing and reimbursement pressure. Both the European Parliament and several Member States have already called for a new updated impact assessment, which the Commission announced in June 2025.

The UWWTD case underscores the urgent need for robust, cross-sectoral impact assessments that factor in the resilience and affordability of medicine supply. Ensuring that future Union initiatives are aligned with the objectives of the Critical Medicines Act is crucial to prevent unintended disruptions, protect patient access and preserve the viability of Europe's pharmaceutical ecosystem.

Recommendations:

1. The regulation should introduce a **"one-stop-shop"** to coordinate European and national funds on critical medicines, to streamline, fast-track approval process with reduced bureaucracy (Article 7).
2. The **MFF should allocate €4 billion to medicine manufacturing** to support upgrades for security of supply or environmental improvements to approximately 150 production sites in Europe and could facilitate the "reshoring" of a limited number of molecules of national security interest to the EU (Article 16).
3. The European Commission should issue **new *ad hoc* State aid and regional aid guidelines** (Article 15) specific to critical medicines for financing projects that are aimed to improve the security of

supply of medicines in Europe both in terms of volume (increase manufacturing of medicines in Europe) as well as in terms of quality (improved manufacturing of medicines in Europe).

4. To avoid undermining the objectives of the Critical Medicines Act, it is also essential to ensure **strong policy coherence across all Union initiatives** that may directly or indirectly impact the supply and availability of critical medicinal products (Article 4), as happened with the Urban Wastewater Directive.

3. Integrating supply security and diversity into demand side measures

Demand-side policies play a crucial role in shaping the economic environment for medicines. Healthcare systems across Europe are under growing pressure to ensure access to life-saving treatments while simultaneously controlling public spending. This has led to the adoption of various cost-containment measures, including clawback schemes, restrictive pricing frameworks, and reimbursement limitations. While these policies aim to ensure affordability, they can also inadvertently result in under-treatment in several therapeutic areas, hinder economic viability of medicines production and endanger security of supply. Striking the right balance between affordability and availability remains a complex and ongoing challenge.

The medicines sector is among the most highly regulated industries, with fixed pricing mechanisms and procurement rules that often prioritise the lowest-cost option in a “winner-takes-all” model. This approach has triggered a downward spiral in medicine prices, threatening the economic sustainability of supply, particularly for generic medicines. In most EU Member States, procurement is a key tool used to generate healthcare savings. However, when procurement is driven predominantly by the lowest price criterion, it places immense pressure on generic medicine pricing, leading to industry consolidation and an increased risk to the security of supply.

Generic medicine manufacturers operate on very tight margins to provide affordable healthcare solutions. In recent years, these companies have been hit by successive cost increases—firstly during the COVID-19 pandemic, then by the energy and gas crisis, high inflation, rising transportation, workforce and input costs, and the growing burden of environmental compliance. All of this has occurred within the constraints of a tightly regulated pricing framework, making it increasingly difficult for manufacturers to adapt and remain viable.

A single manufacturing site may produce hundreds of different medicines, ranging from those on the critical medicines list to other equally essential therapies. These facilities require ongoing upgrades to infrastructure, personnel, and processes, which must be aligned with the broader economic environment. It is therefore essential to look beyond the pricing of individual medicines and consider the sustainability of the economic operator as a whole. Regulatory policies and cost pressures should enable, not hinder, the continued operation of manufacturing sites. The cumulative impact of regulatory and economic decisions can jeopardise the ability of manufacturers to sustain production, not just of individual medicines, but of entire portfolios.

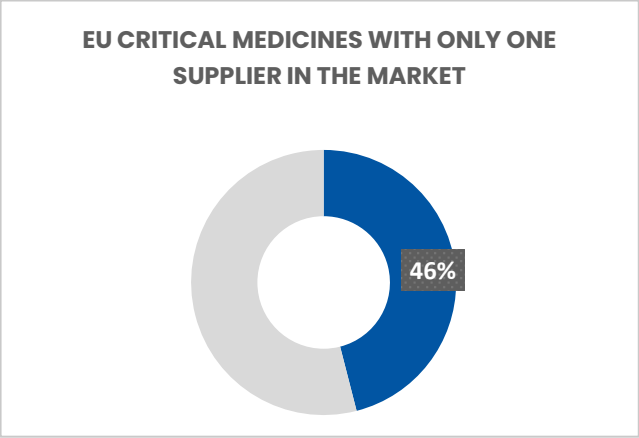
A healthy economic environment must support the viability of manufacturers as a whole, including those producing non-critical but still medically important treatments. Recognising the broader operational context is

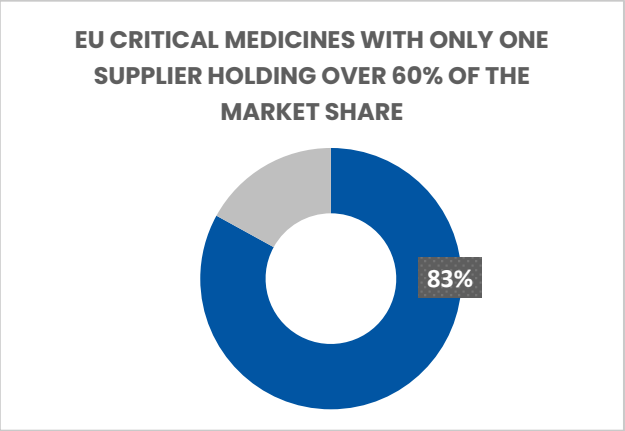
essential to ensuring a resilient and reliable supply of medicines across Europe, as the rate of generic product withdrawals in Europe has increased by 12%, while launches decreased by 3% in 2024 only[15].

I. Public procurement

Public procurement plays a key role in medicine availability and patient access. While Member States' generic and biosimilar medicine market policies have successfully stimulated competition in pharmaceutical markets, mostly at expiry of the originator medicine's exclusivity period, existing policies have failed to stimulate multi-source competition over the long term.

A recent study conducted by TEVA,[16] a Medicines for Europe member, reveals significant vulnerabilities in the EU's supply of critical medicines, as 46% of EU critical medicines have only one supplier in the market. This figure escalates to 83% when considering suppliers holding over 60% of the market share.





This consolidation of supply poses a substantial risk to the resilience of the EU's pharmaceutical supply chain. In the event of a disruption affecting a major supplier, smaller manufacturers may face challenges in scaling up production quickly to meet the increased demand, potentially leading to shortages of essential medicines.

As acknowledged in a Commission study, '*Public procurement of medicines is a strategic policy option to foster competition and improve access to medicines, as well as addressing important further policy objectives, including ensuring security of supply, protecting the environment, and improving crisis preparedness.*'[17] To maintain sustainable competition in the public procurement of critical medicines, it is essential to balance further policy objectives, including cost reduction, supply security and green pharmaceutical design.[18] This has been confirmed by a recent study indicating that higher medicine prices in France could reduce the occurrence of shortages,[19] a consideration that should be well taken into account in tender design for critical medicines. With mounting

[15] Teva, Teva Generics Health Check, European Critical Medicines Supply Diversity Under Pressure (February 2025).
[16] *Idem.*
[17] European Commission, Study on best practices in the public procurement of medicines (December 2022).
[18] *Idem.*
[19] Toulouse School of Economics, Drug Shortages: Empirical evidence from France, Working Paper No 1417 (March 2023).

evidence[20] drawing a clear link between procurement and medicine shortages in the EU, it is high time for the CMA to address the root causes of failing practices in the public procurement of critical and essential medicines, thereby safeguarding patient access to essential treatments.

Mandatory non-price award criteria

The widespread use of single-winner, price-only tenders has made a direct contribution to industrial consolidation as rightly recognised in the proposal for a Critical Medicines Act**. We commend the European Commission for including the mandatory use of award criteria other than price (Article 18(1)),** explicitly referencing supply security criteria, such as diversified suppliers and supply chain monitoring. The reference, however, to **stockpiling obligations** in this provision directly **undermines the overarching supply security objective, given that fragmented and disproportionate stockpiling requirements create artificial barriers within the market, impose rigid costs for manufacturers and consequently limit their flexibility to mitigate shortages.** As evidenced in the Stockpiling Measures section of this document (4.), these obligations disproportionately impact manufacturers of low-margin essential medicines generating environmental waste from expired unused medicines, economic unsustainability due to uncompensated costs, and reduced supply flexibility from nationally locked stocks to mitigate shortages.

Additionally, **non-price award criteria should by default include additional considerations, such as environmental and sustainable manufacturing criteria, and corporate sustainability criteria,**[21] in order to promote sustainable manufacturing practices and ensure fair competition. Allowing discretionary application of environmental criteria, as suggested in Article 18(4) of the proposal, risks creating a fragmented procurement environment, which could impose additional burdens on suppliers operating across multiple EU countries. Such fragmentation may lead to increased complexity and costs, as suppliers would need to navigate and comply with a patchwork of divergent requirements, potentially undermining the efficiency and effectiveness of the procurement process.

Recommendations:

1. Ensure that non-price award criteria for the public procurement of critical medicines also mandatorily include **environmental, corporate sustainability and sustainable manufacturing criteria** (Article 18(1) & (4)), to streamline procurement processes across EU Member States.
2. **Delete the reference to stockpiling obligations** in Article 18(1) as it directly undermines the overarching supply security objective of this provision.

[20] See European Commission: Study on medicines shortages (2021) ; the Study on best practices in the public procurement of medicines (December 2022); and the Strategic Report of the Critical Medicines Alliance (February 2025).
[21] Medicines for Europe, Medicines Procurement Reform: Strengthening supply security through EU Guidance (February 2024).

Streamline the interpretation of award considerations beyond pricing

To further enhance the effectiveness of the proposed procurement measures, it is crucial that award criteria beyond price are consistently applied across Member States. This ensures that contracting authorities evaluate suppliers against the same standards, promoting fair competition and increasing legal certainty for critical medicine manufacturers. **Therefore, the final text of the CMA should empower the European Commission to issue an implementing act specifying the non-price criteria that can be considered by contracting authorities within a short timeframe after the Act enters into force.** This alignment would not only streamline the procurement process but also encourage suppliers to invest in more resilient and sustainable supply chains, ultimately benefiting patients across the EU. To further endorse streamlining amongst contracting authorities' practices, any decisions not to apply the rules and criteria outlined in Articles 18(1-3), should also be reported to the **Critical Medicines Coordination Group (Article 18(5)).**

This should also inform forthcoming discussions on the **revision of the Public Procurement Directive (2014/24/EU).**[22] Recognising the pharmaceutical sector as an economic growth driver and a strategic industry within public healthcare expenditure is essential to ensure that procurement rules align with its unique needs and facilitate tendering processes that guarantee supply security and medicine availability. To uphold a competitive pharmaceutical landscape in Europe, discussions on medicine availability must extend beyond CMA-covered medicines alone and address the broader financial sustainability of the off-patent industry. This broader perspective is essential, as focusing solely on selected categories risks fragmenting public procurement rules across critical medicines (with or without confirmed vulnerability status), medicines of common interest, and those not included under the Act.

Consequently, there is an urgent need for sector-specific rules that extend beyond the procurement of critical and essential medicines. These rules should be established through a delegated act included in the revision of the Public Procurement Directive to ensure tailored and effective governance.

Recommendations:

1. **Ensure that non-price award criteria are interpreted and specified by the European Commission**, in the form of an implementing act (Article 18(1)). This is important to ensure harmonised application of non-price award criteria by contracting authorities.
2. Foster streamlined processes amongst contracting authorities, by introducing an **obligation to report to the Critical Medicines Coordination Group (Article 18(5)) any decisions not applying the rules of Article 18(1) – (3).**

Multi-winner tenders and demand predictability

To ensure the Act achieves its objectives, non-price award criteria should be coupled with the **introduction of multi-slot tenders for critical medicines**, **where feasible**. This approach would enable multiple suppliers to

[22] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC.

actively participate in the market, thereby enhancing competition and securing supply continuity and diversification. As the majority of medicine tenders result in single-winner contracts, accounting for up to 84% of all contracts awarded in some cases,[23] and reaching even 88% in some regions in Italy,[24] such practices hamper competition and jeopardise supply security, given that other suppliers do not have any incentive to maintain active production to mitigate shortages failing to win the tender. Implementing multi-slot tenders would allow for the allocation of contracts to multiple suppliers, thereby reducing dependency on a single source and enhancing the resilience of the supply chain. For this mechanism to be successful in practice, tender design should follow **clear rules on slot division,** foreseeing **demand predictability and minimum binding quantities,** regarding the volumes to be purchased, and also sufficient **lead times**, that will allow suppliers to deliver in a timely manner.

Recommendations:

1. Introduce **mandatory multi-slot tenders where possible** for critical medicines (Article 18(1)).
2. Introduce clear rules on tender division into slots and increase **demand predictability** by ensuring sufficient lead times from contract signature until the first medicine supply, **clear volume estimates and minimum binding quantities.**

Possibility to adjust prices in duly justified cases

Moreover, the possibility of adjusting pricing in tenders becomes increasingly significant in scenarios involving prolonged timelines or multiannual tenders. Fluctuations in the economic landscape, such as inflation and other market shocks, can lead to substantial increases in production and distribution costs. Introducing the **ability to adjust prices in duly justified cases enables suppliers to mitigate these economic challenges while ensuring a consistent supply of medicines**. This flexibility ultimately fosters a procurement process that is both resilient and sustainable, ensuring patients' access to essential medications. Hence the provision of Article 18(1) should be adjusted to include such a possibility. This would also be in line with the European Parliament IMCO Committee's draft own initiative report on public procurement.[25] Including such a mechanism that is effective on the ground and delivers the necessary adjustments needed will not only mitigate economic challenges and ensure consistent supply but will also further ensure long term competitive tender bids (i.e. lower prices), as it would limit the need to factor potential significant economic fluctuations into tender bids.

[23] European Commission, Study on best practices in the public procurement of medicines, September 2022.
[24] IQVIA, Valore dei Biosimilari, Sostenibilità del Sistema e Prospettive Future.
[25] European Parliament, Committee on the Internal Market and Consumer Protection, Draft Report on Public procurement (2024/2103(INI)).

Recommendations:

1. Introduce the ability to adjust pricing in tenders which are extended or multiannual tenders (Article 18(1)), to allow critical medicine suppliers to absorb substantial increases in production, while ensuring supply continuity.

Technical recommendation on the application of localisation criteria for medicines with confirmed supply vulnerabilities

Regarding **critical medicinal products identified as having supply chain vulnerabilities, i.e. those dependent on a single or limited number of third countries (Article 18(2)),** it is important that the provision, if applied, supports resilient supply chains while remaining compatible with open and competitive markets. To ensure effective implementation of this provision, co-legislators should focus on its technical design of the measure to ensure that competitive tendering processes are not disrupted. This includes ensuring the **availability of multiple slots for both EU and non-EU manufacturers when feasible, with multi-winners in both categories.**

Specifically, for tenders involving larger production volumes, multiple separate slots should be foreseen, and allocated between EU and non-EU manufacturers, with multi-winners in both slots, to support EU production while also ensuring supply diversification and safeguarding competition. Furthermore, in the absence of sufficient bidder interest, provisions should allow participation in tenders to be open to all interested parties, thereby ensuring the continuity of medicine supply. **This technical recommendation should apply equally to the procurement of products of common interest in Article 18(3),** where applicable and justified.

Moreover, to provide both suppliers and contracting authorities with greater predictability, it is essential that the final text of the Act clearly defines what constitutes a *'significant proportion'* of manufacturing within the EU. This is particularly important given the differential treatment foreseen envisioned for suppliers falling under this category.

Recommendations:

1. Safeguard competitive tendering processes for critical medicines with a vulnerability assessment, by introducing the division of tenders into multiple slots for EU and non-EU manufacturers, with multi-winners in each slot, where possible (Article 18(2)). This technical recommendation should apply equally to the procurement of products of common interest in Article 18(3), where justified by market analysis and public health considerations.
2. Ensure legal clarity by clarifying further what constitutes a 'significant proportion' of manufacturing in the EU means in article 18(2)).

II. National programmes supporting security of supply of critical medicinal products

Public procurement is an important tool for the purchase of critical medicines and medicines of common interest; however, as mentioned above, not all medicines are purchased through tenders which are largely reserved for direct hospital purchasing in the majority of EU Member States. Many critical medicines are being made available to patients through (retail) pharmacies, where national pricing and reimbursement (P&R) policies play a key role, as prices of medicines in almost all EU countries are regulated and tightly controlled. Importantly, even in hospital settings, price regulation plays a central role: regulated prices (list prices) act as a ceiling price which manufacturers have to respect to participate in tenders or supply hospitals, thereby shaping both market entry and procurement outcomes.

Article 19 (1) allows Member States to include P&R considerations within their national programmes supporting security of supply. We welcome this measure, however, given their importance, **P&R considerations should be a mandatory component of these national programmes,** alongside public procurement procedures. This approach would enable the Critical Medicines Group to holistically monitor and assess the impact of market policies on the availability of critical medicines across the EU. Such integration would facilitate informed discussions and the issuance of opinions on the application and effects of these policies, thereby enhancing the overall security of supply.

Furthermore, to enhance transparency on national P&R measures applicable to critical medicines, such programmes should also be empowered to **review any potential price freezes which may be imposed on critical medicines** to determine whether these are justified by economic conditions and in line with overall supply security recommendations. **This would be consistent with the objectives of the Transparency Directive (89/105/EEC)**,[26] aiming to ensure transparency in the national P&R procedures and preventing delays or barriers to the access of medicines across the EU Member States.

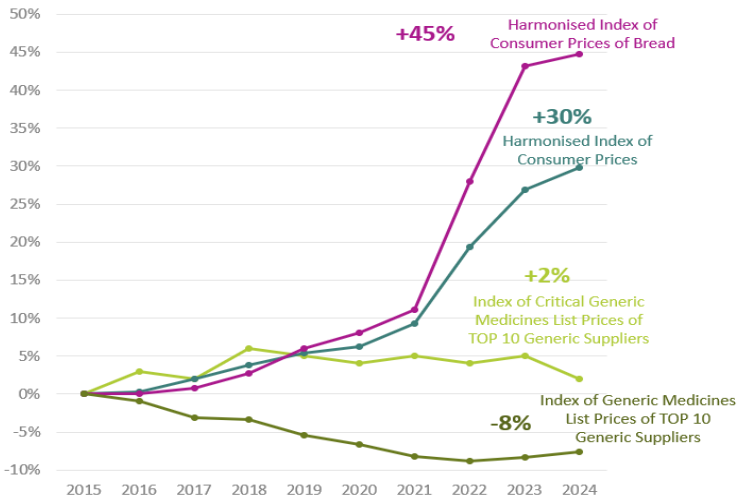
These programmes should also be **empowered to review the impact of cost containment measures such as clawbacks on security of supply.** These measures should be assessed and reported to the Commission as required by the Transparency Directive. The CMA should require Member States to correct the measure if it is deemed to reduce security of supply or to increase supply chain consolidation.

To strengthen supply security through national pricing and reimbursement (P&R) policies, pricing regulation must be more adaptable to the life cycle status and market supply dynamics. A life cycle-based model ensures that the pricing of critical medicines aligns with actual supply conditions and the number of active suppliers. Discussion on diversified approaches should be encouraged, and exchange of best practices fostered through the Critical Medicines Group and NCAPR.

For instance, **the dynamic pricing model**, **so called Canadian 'ladder' model,** adjusts prices based on competition—prices rise when the number of competitors decreases, helping sustain market viability. Similarly, when supply-side pressures emerge, mechanisms should be in place to send a **price signal** (higher prices), incentivising additional suppliers, and fostering competition. This approach enhances stability and ensures continued availability of essential medicines.

[26] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

Further security of supply criteria in national pricing law should also include an assessment of supply consolidation by the national medicines agency which should be able to require a change to the pricing law to reverse consolidation or to encourage more diversity of manufacturers to supply the national market as initiated in Germany. The German Law known as *'Arzneimittel Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz' (ALBVVG*), passed in July 2023, aims to mitigate supply shortages and improve the availability of essential medicines. This law introduces several measures, including adjustments to pricing regulations for specific categories of drugs. If there are too few suppliers for a critical medicine, the reference price or the price moratorium may be increased by up to 50% on a one-off basis to help stabilise supply. The Federal Institute for Drugs and Medical Devices (BfArM) plays a central role in managing medicine shortages in Germany. It is responsible for monitoring supply disruptions and maintaining a national database of current shortages. BfArM also collaborates with stakeholders to coordinate responses and ensure continued patient access to essential medicines.[27]



Top 10 generic medicine suppliers provide 48% of whole generic medicines volume

Finally, **an inflation adjustment mechanism should be integrated into national or sub-national pricing rules** as off-patent medicines suffered from price deflation during the recent post-covid (30%+) inflationary cycle, as shown in the graphic above. Such mechanisms should be monitored by national programmes and reported to the Critical Medicines Group.

Recommendations:

1. Introduce an obligation for Member States to include P&R measures applicable to critical medicines in their national programmes supporting security of supply (Article 19(1)) given the importance of such measures.
2. Empower national security of supply programmes to review price freezes and cost containment measures applicable to critical medicines to enhance transparency in Article 19(1).
3. National pricing rules should include an inflation adjustment mechanism and a separate assessment of supply consolidation by the national medicines agency, which should be able to require a change to the pricing law to reverse consolidation or to encourage more diversity of manufacturers to supply the national market. These should be monitored by national programmes and reported back to the Critical Medicines Group. This should be specified in Article 19.

[27] In accordance with the German Act to Combat and Improve the supply of medicines (ALBVVG).

4. Ensuring solidarity to tackle shortages - Stockpiling measures

Several steps have been introduced to facilitate shortage mitigation coordination between Member States, in the EMA extended mandate legislation.[28] Building on that legislation, the Act should address national stockpiling mandates, as they constitute a quantitative restriction to trade and must therefore be proportionate to their public health objective, in line with EU Internal Market rules. The European Commission's proposal mandates that contingency stock requirements must be **'proportionate and respect the principles of transparency and solidarity'.**

Evidence, including from the HERA AMR feasibility study on stockpiling,[29] shows that stockpiling requirements disproportionately affect manufacturers of older, low-margin essential medicines including antibiotics. For these products, stockpiling is often financially unfeasible and leads to a cascade of long-term structural risks in four critical areas: environmental waste, economic sustainability, supply flexibility, and manufacturing viability.

Firstly, large volumes of medicines might expire unused due to poor demand forecasting, particularly in categories such as antibiotics. According to a survey conducted with Medicines for Europe members, due to national contingency stock obligations, today, for every 100 medicines produced, 10 are destroyed. This is further compounded by the difficulty of accurate predictability, especially as seasonal trends can vary significantly from year to year.

Secondly, mandatory stockpiling shifts the cost burden onto manufacturers without compensation, especially in the generics sector where margins are tight. Without predictable and fair remuneration schemes, companies may be forced to exit markets, reducing competition and ultimately harming patients. These challenges are made worse by disproportionate penalties for non-compliance, which further disincentivise supply.

Thirdly, fragmented stockpiling reduces supply flexibility. When stock is locked at the national level, companies are unable to reallocate medicines according to real-time needs. This results in avoidable shortages in some countries and oversupply in others—undermining the EU's ability to respond cohesively to demand surges. The use of digital leaflets and other permanent regulatory flexibilities can support the timely redistribution of medicines within the EU through solidarity mechanisms, such as the one developed by the EMA Medicines Shortages Steering Group (MSSG).

Critically, claims that stockpiling reduces shortages or boosts capacity are not backed by evidence. Studies from the European Commission (Technopolis)[30] and evidence from France[31] show that shortages are typically short-lived and localised, often resolved through routine supplier adjustments. What improves resilience is a diversified supplier base, sustainable pricing, and smart procurement—not excessive stock accumulation. Flexibility to share stocks across EU countries is also essential to ensure coordinated responses and efficient use of resources.

The European Commission's proposal usefully **highlights that contingency stock requirements must be proportionate and respectful of transparency and solidarity principles**. However, the implementation of Article

[28] Notably the creation of a European committee to cooperate on medicines shortages (MSSG): https://www.ema.europa.eu/en/news/regulation-emas-extended-mandate-becomes-applicable.

[29] European Commission: European Health and Digital Executive Agency and McKinsey Solutions, HERA AMR feasibility study on stockpiling – D6/D7 – Final report, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2925/208305.

[30] European Commission: Directorate-General for Health and Food Safety, Ecorys BV, Milieu Law and Policy Consulting, Technopolis Group, Jongh, T. d. et al., Future-proofing pharmaceutical legislation – Study on medicine shortages – Final report (revised), Publications Office of the European Union, 2021, https://data.europa.eu/doi/10.2875/211485.

[31] Dubois, Pierre & Majewska, Gosia & Reig, Valentina, 2023. "Drug Shortages: Empirical Evidence from France," TSE Working Papers 23-1417, Toulouse School of Economics (TSE).

20 requires targeted improvements to address growing structural risks and fragmentation resulting from national stockpiling mandates, particularly in the off-patent sector.

To address these issues, Article 20 should be strengthened by requiring contingency stocks to be reported through national programmes to ensure integration with broader preparedness efforts. Medicines subject to these obligations must be exempt from parallel exports to safeguard domestic supply. Companies that engage in solidarity stock transfers to other Member States should be exempt from fines; fines in general should be reserved for abusive behaviour and remain proportionate to market value, not hinder supply security. If any EU stockpile is to be established, it should replace national obligations for the same medicine, to avoid duplication, excessive costs, and complexity for manufacturers. To prevent supplier consolidation, fair remuneration for stockpiling should reflect real costs (including storage, inflation, and losses due to expiry) to support sustainable supply. Regulatory flexibilities should facilitate simplified cross-border redistribution of contingency stocks to enable solidarity without bureaucratic delays.

In addition, the scope of stockpiling should be defined based on scientific vulnerability assessments (e.g. single-source or historical shortages) and limited to a maximum of two months' national average consumption. National stockpiling mandates should be notified ex ante to the Commission, with automatic proportionality reviews above threshold levels, and the Commission should assess proportionality upon request from other Member States. Expiry-adjusted risk parameters should be incorporated to avoid unnecessary waste and stock rotation mechanisms should be promoted to minimise waste and limit environmental impact. The UK's Essential Medicines Buffer Stock (EMBS) scheme is one reference model, where government-owned stock is rotated by releasing inventory into the commercial supply chain and replenishing it to maintain minimum shelf life. Authorisation should be facilitated for a single EU presentation and packaging for critical medicines, coupled with an e-leaflet, with access to at least equivalent pricing and reimbursement (P&R) conditions across Member States.

Recommendations:

1. Require contingency stocks to be reported as part of national programmes supporting the security of supply of critical medicines (Article 19). This will ensure transparency and integration of stockpiling efforts into broader national preparedness strategies.
2. Exempt medicines subject to contingency stockholding obligations from parallel export activities (Article 20). This will safeguard domestic supply and reinforce the purpose of contingency reserves.
3. Provide exemption from fines for companies that respond to shortages in another Member State through solidarity stock transfers (Article 20). This will encourage cross-border cooperation and disincentivise penalties that undermine emergency supply actions.
4. Prevent supplier market consolidation by ensuring fair remuneration for stockpiling obligations and minimising waste and write-offs through improved stock management (Article 20). This will promote a sustainable and competitive supply base for contingency stocks.
5. Introduce permanent regulatory flexibilities for medicines in the scope of contingency stocks, in order to enable a solidarity mechanism between national stockpiles (Article 20). This measure will support coordinated responses to shortages across Member States.

5. Collaborative procurement

I. General remarks

Collaborative procurement of critical medicinal products and other medicines of common interest can serve as an approach to enhance their security of supply in the European Union. However, as this method poses multiple challenges, it should explicitly remain a voluntary option for Member States to join and include clear and quantifiable criteria under which the Commission may initiate joint procurement procedures.

The extension of collaborative procurement rules to critical medicines and medicines of common European interest **should focus on small volume medicines where there is a barrier to supplying smaller Member State markets due to volume constraints and should be quantified when using this instrument.** While collaborative procurement can be beneficial, it should not be used as a means to further reduce the prices of off-patent medicines. Doing so would place additional pressure on suppliers who are already struggling to manage the continuously rising costs of manufacturing. At the same time, if any EU stockpile is to be established, it should replace national obligations for the same medicine, to avoid duplication, excessive costs, and complexity for manufacturers.

Moreover, there are many **regulatory barriers** to collaborative procurement of off-patent products such as national packaging and country-specific paper leaflets, **therefore permanent regulatory flexibilities should be granted including, but not limited to, the use of e-leaflets, the harmonisation of pack sizes, labelling flexibilities.**

Furthermore, to ensure a level playing field between national and collaborative procurement practices**, it is vital that the same general procurement rules foreseen in the Act in Article 18 apply to collaborative procurement practices as well** – multi-winner, clear volume allocation and award criteria for the Most Economically Advantageous Tender (MEAT) and security of supply considerations – **mirroring the standards used in public procurement in the Act**. Finally, joint procurement and procurement on behalf or in the name of Member States **should not conflict with national procurement or established market arrangements, to avoid market disruptions that could lead to shortages.** The **intention to initiate collaborative procurement should be announced well in advance**, in order not to disrupt supply security.

For the same reason, Member States should honour their commercial obligations in ongoing national contracts or market arrangements. To ensure the effectiveness of European or cross-border joint procurement initiatives, it is imperative **that Member States refrain from conducting parallel national or subnational tenders for the same medicinal products.** This principle is underscored by lessons learned from previous experiences, notably the Commission's Joint Procurement on COVID-19 intensive care unit (ICU) medicines. In that instance, the simultaneous running of competing national tenders led to inefficiencies, including coordination challenges and increased uncertainties for manufacturers, ultimately undermining the security of supply for European patients. Therefore, a coordinated approach, free from conflicting procurement activities, is essential to maximise the benefits of joint procurement efforts and to ensure equitable and reliable access to critical medicines across the EU. Finally, the initiation of collaborative procurement processes should be transparent and a preliminary consultation phase involving potential participating manufacturers should take place.

Recommendations for Article 20:

1. The deployment of collaborative procurement instruments should focus **small volume medicines** where there is a barrier to supplying smaller Member State markets due to volume constraints and should be quantified when using this instrument.
2. **Permanent regulatory flexibilities** need to be granted to facilitate collaborative procurement, including but not limited to leveraging ePI, and lifting national packaging and labelling restrictions.
3. Collaborative procurement design rules should aim at securing supply, not driving unsustainable prices. Design rules should mirror the standards applicable to national procurement proposed under the Act, including multi-winner, clear volume allocation and award criteria for the Most Economically Advantageous Tender (MEAT) and security of supply considerations such as clear binding purchasing commitments.
4. Collaborative procurement should **not conflict with national procurement or established market arrangements**, to avoid market disruptions that could lead to shortages.
5. The intention to initiate collaborative procurement should be announced well in advance, to not disrupt supply security.
6. Member States should honour their commercial obligations for ongoing national contracts or market arrangements.
7. Member States should guarantee there are no competing national or subnational tenders when participating in a European or cross-border collaborative procurement.

II. Need for further clarification in collaborative procurement provisions

The Articles on collaborative procurement (Articles 21-24) also need further clarification and additional specifications to function in practice. Regarding procurement conducted on behalf of, or in the name of, Member States (Article 22(2)) and joint procurement (Article 23(3)), **the criteria under which the Commission would assess whether the procurement processes contribute to improving the security of supply require further clarification.** As currently drafted, the text may lead to legal uncertainty and unintended confusion. A more precise delineation of these criteria is essential to ensure transparency, consistency, and effective implementation of procurement strategies aimed at enhancing the security of supply.

At the same time, it is not sufficiently clear for either of these instruments who the contracting authority would be, how stocks would be distributed to Member States - especially where joint procurement is concerned - or where the stock would need to be stored, insofar as the purchasing process is involved - issues that have direct implications on the liability of the purchaser, creating uncertainty for medicine suppliers. While Article 24 reads that this should be agreed between the Member States and the Commission, this approach needs further clarification, as the suppliers of critical medicines and essential products need legal certainty on these crucial aspects of collaborative procurement processes.

Moreover, as indicated previously, collaborative procurement should not run in parallel to other national or subnational tenders on the same products and **should also include clear volume estimates and minimum binding quantities** to increase demand predictability. However, as shown in the provisions of Article 22(6) and 23(6) respectively, such a possibility would be subject to the Commission's discretion and not applicable by default when the Commission procures jointly or on behalf of, or in the name of, Member States, undermining directly the supply security objective of the Act itself and creating further complications for suppliers.

Where joint procurement is concerned, Article 23(2) states that such processes may also be initiated **at the Commission's initiative, without clarifying further what type of prior assessment is needed and the necessary thresholds required for such an action to be triggered.** This provision stresses that the Commission's initiative alone suffices to initiate joint procurement actions. However, should participating Member States choose not to purchase through the joint tender, as observed during the joint procurement of COVID-19 intensive care unit (ICU) medicines, the absence of coordination could lead to uncertainties for manufacturers. Without sufficient demand guarantees, manufacturers may face challenges in managing stock levels, potentially impacting the overall security of supply of critical medicines and essential medicinal products.

Recommendations:

1. The Commission should provide clearer, **well-defined criteria for assessing how procurement conducted on behalf of Member States** (Article 22(2)) and joint procurement (Article 23(3)) contribute to improving supply security.
2. The Act needs to **further delineate rules regarding stock distribution, storage and liability amongst the Commission and participating Member States** for collaborative procurement procedures to ensure foreseeability and legal clarity for suppliers (Article 24).
3. Collaborative procurement processes should include **clear volume estimates, minimum binding quantities and sufficient lead times** to increase demand predictability for suppliers (to be defined in a new Article 20a).
4. The Act should **further clarify the criteria based on which the Commission may take a joint procurement initiative,** providing measurable thresholds for these processes to be triggered (Article 23).

6. Support international partnerships

In 2024, the European Union exported **€313.4 billion** worth of medicinal and pharmaceutical products - a 13.5 % increase from 2023 - while imports grew modestly by only 0.5 %, totalling **€119.7 billion** As a result, the EU achieved a **record-high trade surplus of €193.6 billion** in this sector, underscoring the EU's dominant position in global pharmaceutical trade.[32]

[32] Exports of medicinal and pharma products up by 13.5% - News articles - Eurostat.

Securing **robust and diversified medicines supply chains** is essential for Europe to guarantee the continuous and equitable supply of medical products, both within the EU and globally, including during times of crisis. This is critical not only for safeguarding public health, but also for reinforcing the resilience of Europe's health systems and pharmaceutical sector.

As the **COVID-19 pandemic** demonstrated, trade restrictions, supply bottlenecks and uncoordinated national responses can severely disrupt access to essential medicines, putting patients at risk and revealing the fragility of global supply networks. These lessons highlight the need for international cooperation and better coordinated preparedness to prevent similar disruptions in the future.

To ensure timely, affordable, and quality-assured treatments at scale, a **transparent, predictable and resilient trade and regulatory environment** is indispensable. Making this a core priority across the EU's internal and external health and trade policies is critical to guarantee continued access to essential medicines.

Pharmaceutical supply chains rely on a **vast, interconnected global network** to produce and deliver medicinal products to patients. Inputs - including components and specialised equipment - are sourced from hundreds of locations, with more than 350 elements often required from suppliers, local manufacturers, or in-house production before a medicine reaches the local warehouse.

Enhancing cooperation with the EU's key trading partners is fundamental to strengthening supply chain security and reinforcing Europe's role in international pharmaceutical trade. The EU should continue to champion open trade and multilateral cooperation by promoting resilient, diversified and secure supply chains, including the recognition of equivalent regulatory standards with global partners. Continued engagement with strategic stakeholders in third countries is vital to safeguarding supply continuity and enabling coordinated, solidarity-based responses to future health emergencies.

Article 27 of the proposed Critical Medicines Act marks an important step by recognising the role of **international partnerships** in diversifying supply chains. However, this provision should be strengthened to reflect a more structured, strategic and forward-looking trade policy approach that proactively supports the EU's health security and industrial resilience objectives, while also creating additional opportunities for EU exports.

To this end, the Article should include an explicit obligation for the European Commission to assess and promote the inclusion of **health security chapters** in free trade agreements and other relevant international cooperation frameworks.

These chapters should include specific commitments to **cooperate during public health emergencies** and to **prevent export restrictions** on critical goods, including finished medicines, active pharmaceutical ingredients (APIs), and other materials essential for the manufacture and distribution of medical products.

The COVID-19 pandemic demonstrated the importance of measures such as **green lanes and digital documentation** to overcome trade disruptions, reduce delays and ensure the timely delivery of essential medical goods, including vaccines.

Moreover, such chapters should prioritise **regulatory cooperation and convergence as a central pillar of pharmaceutical trade policy.** The European Union should prioritise the importance of moving towards regulatory convergence by encouraging the harmonisation of regulatory standards, promoting regulatory reliance, and reviewing regulatory systems for optimised approval processes to accelerate access to medicines, eliminate unnecessary duplications and improve efficiency and predictability.

In this framework, **Mutual Recognition Agreements (MRAs) covering pharmaceutical Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP**) are crucial instruments that can support resource efficiencies for regulators, reduce duplication of inspections, and shorten timelines for the importation and distribution of medicines. The EU should consider expanding the scope of existing MRAs where appropriate, as well as initiating new MRAs with countries that maintain high regulatory standards and compatible systems.

In the context of **EU enlargemen**t, the alignment of pharmaceutical regulations must be treated as a strategic priority. For accession agreements, the EU should **accelerate the integration and implementation of its pharmaceutical regulatory framework with candidate countries such as Ukraine and the Western Balkan states.** Early and structured regulatory convergence is essential not only to ensure patient safety and quality standards across borders but also to facilitate the integration of these countries into the EU single market and to strengthen the resilience and diversification of EU pharmaceutical supply chains.

Recommendations:

Article 27 of the Act needs to include obligations to:

1. Consider and promote the inclusion of **health security chapters** in free trade agreements and any other relevant international cooperation frameworks, covering elements such as **coordination during public health emergencies, prevention of export restrictions and enhanced regulatory cooperation**.
2. Support the i**ntegration and implementation of the EU pharmaceutical acquis in candidate countries** such as Ukraine and the Western Balkan states, as part of their accession processes.

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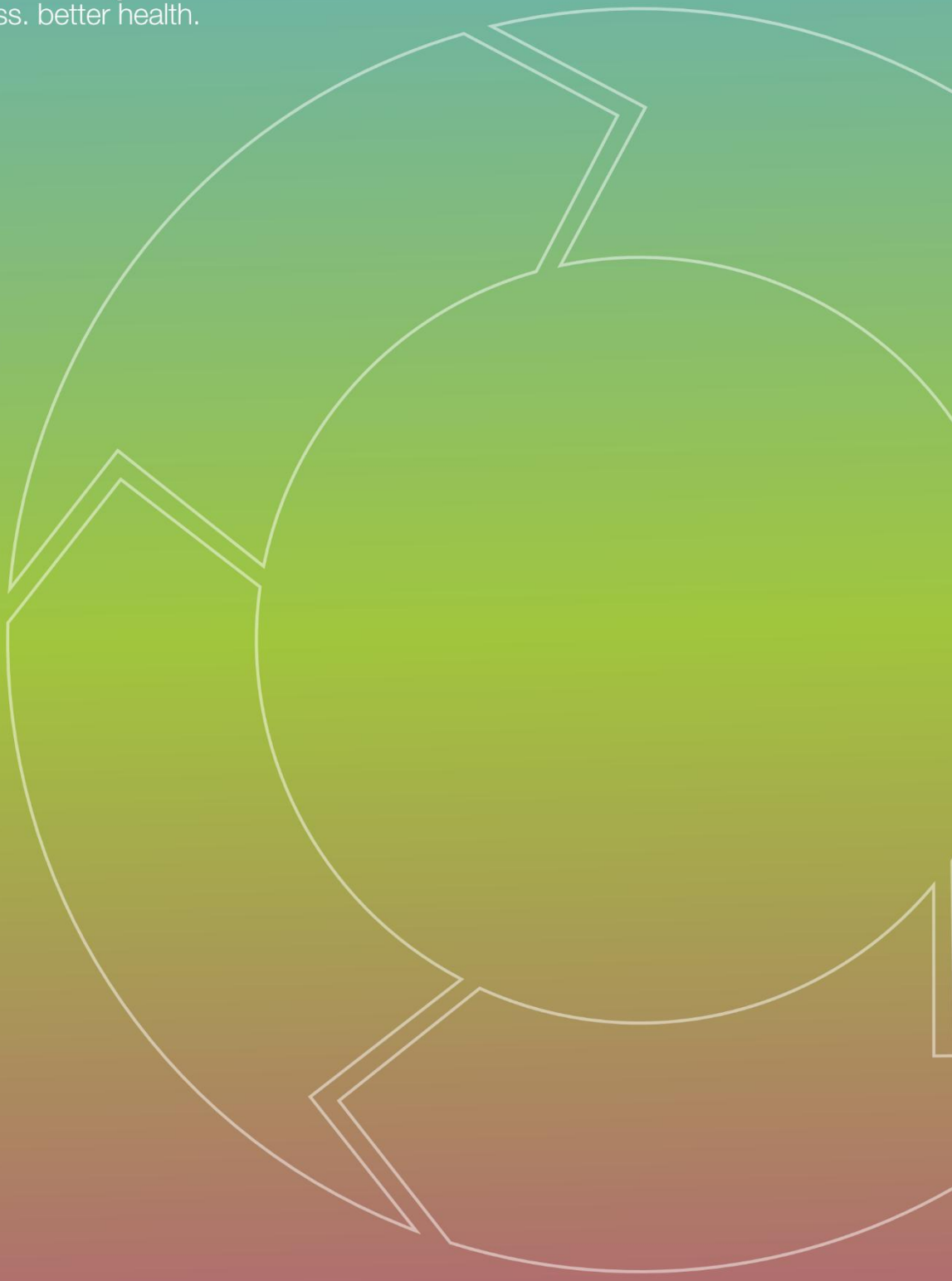

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