Strategic Report of the Critical Medicines Alliance

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Introduction: a shared diagnosis

Shortages of Critical Medicines have been on the rise for many years globally. They are a concern for all EU Member States. Major recent events, such as the COVID-19 pandemic or the invasion of Ukraine, have exacerbated their prevalence and duration, and have undermined patient's timely access to high quality care. The root causes for shortages are complex and variable, depending on the type of product. Unexpected increases in demand, manufacturing and quality issues, closures or relocations of manufacturing sites are all potential reasons for the occurrence of shortages of a specific product.

The EU has already taken steps to respond to these shortages, notably by developing a more coordinated approach at EU level. The European Medicine Agency's extended mandate and its work via the Executive Steering Group on Shortages and Safety of Medicinal Products[1] ('MSSG') on monitoring shortages and building the Voluntary Solidarity Mechanism[2] ('VSM') have been instrumental in developing such an approach. In December 2023, the European Commission published the first Union List of Critical Medicines, together with the European Medicines Agency (EMA) and the Member States' Heads of Medicines Agencies (HMA)[3]. The current version contains over 260 active substances. It is updated on an annual basis, covering a wide range of therapeutic areas targeting both communicable and non-communicable diseases, thus providing a common frame of reference for the fight against shortages at EU level. Additional measures to address shortages and strengthen the supply of Critical Medicines are contained in the proposed review of the pharmaceutical legislation, and others should be set out by the new Commission's proposal for a biotech act aiming at striking the right balance between competitiveness and innovation in the pharmaceutical sector across the whole value chain[4].

Nevertheless, it has become clear that not all reasons for shortages had been considered for policy intervention at EU level. There is a need to look 'upstream' at vulnerabilities in the manufacturing supply chains of Critical Medicines and to adopt a more proactive industrial policy in this field. This focus is reflected in the Commission Communication on "addressing shortages of medicines in the EU" of October 2023, which has announced the setting up of a Critical Medicines Alliance so as to ensure adequate stakeholder consultation on this matter. This has also been followed up by the new Von der Leyen Commission proposal for a "Critical Medicines Act" (the "Act")[5]. The objective of the Act is to develop a coordinated, European industrial framework to prevent and mitigate shortages of the most Critical Medicines, which are caused by structural issues that cannot be addressed by any regulatory interventions.

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[1] Executive Steering Group on Shortages and Safety of Medicinal Products | European Medicines Agency (EMA)
[2] EMA takes further steps to address critical shortages of medicines in the EU | European Medicines Agency (EMA)
[3] First version of the Union List of Critical Medicines agreed to help avoid potential shortages in the EU | European Medicines Agency (EMA)
[4] Announcement of an EU Biotech Act
[5] Political Guidelines

The Critical Medicines Alliance

To discuss the industrial challenges behind shortages of Critical Medicines, the Critical Medicines Alliance was set up and launched in April 2024. The Alliance brings together stakeholders from health professions, industry and civil society and representatives from Member States[6]. It has been set up for five years. The Alliance aims to identify key challenges and formulate recommendations for areas and priorities for action, proposing solutions to strengthen the supply of Critical Medicines in the EU and the development of a dedicated industrial policy focusing on Critical Medicines.

The Steering Board of the Alliance has prepared this Strategic Report for the consideration of the Alliance Forum. [*Following its meeting on 12 February 2025, the Alliance Forum has confirmed its broad endorsement of the Report*][7].

The main focus of the Strategic Report is to put forward strategic recommendations to the Commission, Member States and the Alliance's stakeholders on actions and measures that could be implemented to support the strengthening of Critical Medicines manufacturing in the EU and to ensure strategic partnerships with non-EU countries to strengthen the supply chain of Critical Medicines. The Report was built on recommendations developed by thematic Working Groups of the Alliance and should be seen as a key contribution for the preparation of a future Critical Medicines Act.

Key industrial challenges for Critical Medicines

While shortages can affect any type of medicine, they disproportionately impact older, off-patent and generic medicines. This issue stems largely from the low profit margins associated with these products[8], which discourage investments in robust manufacturing capacities. EU health systems have increasingly relied on generic medicines, prioritising procurement at the lowest cost to reduce the burden on national health care budgets. However, understanding the root causes of shortages of Critical Medicines requires a clear distinction between the market dynamics of generic medicines/off-patent medicines and those of innovative/on-patent medicines

The Union List of Critical Medicines, as it stands, mostly comprises generic, off-patent medicines that no longer benefit from intellectual property rights or other regulatory data protections. These affordable medicines have often become 'staple' products of EU health systems, but are increasingly produced in ways that heighten vulnerability. Many Critical Medicines are supplied by only one or two manufacturers, leaving supply chains highly fragile and dependent. These

[6] Terms of Reference of the Critical Medicines Alliance
[7] Opinions of Alliance members are available on the following link [...], [including dissenting ones]
[8] Future-proofing pharmaceutical legislation – study on medicine shortages, European Commission, 2021

suppliers have often moved production of their finished product outside of the EU and/or source their API from outside the EU. As a result, the EU is reliant, for many of its Critical Medicines, on a limited number of APIs suppliers or manufacturers, many situated outside of the EU. For generic medicines, it has been calculated that between 60 to 80% of the API production has been outsourced to China over the recent years and an increasing part of other inputs to the manufacturing supply chain are being outsourced to Asia[9].

This dynamic has increased the vulnerability of the EU supply chains of generic medicines. Any disruption - whether due to manufacturing or quality issue, natural disasters, geopolitical conflicts or the withdrawal of a marketing authorisation holder from the market - can lead to a shortage of a critical medicine in the EU. Innovative medicines, in contrast, have retained a much larger footprint in the EU but represent only 10-20% of the EU list of Critical Medicines.

On this basis, the Alliance identified and discussed the following key industrial challenges:

1) Overreliance on a limited number of geographical locations[10] for the provision of API and raw materials, which is of high importance for both generics and originators;
2) Erosion of the EU manufacturing base, starting upstream of the supply chain as well as for marketing authorisation holders - especially for generics (90% of the Critical Medicines list), but also for innovative medicines;
3) Clear market consolidation which encourages single supplier sourcing inside and outside of the EU;
4) Lack of competitiveness and investment in the European API industry as well as in the generics industry;
5) Trend towards a fragmentation of the industrial value chain, with a clear separation between upstream activities producers (intermediates and API producers) and high-value downstream activities producers (formulation and packaging). This results in limited visibility and investment potential for upstream API and intermediates suppliers.

Proposed way forward

The Critical Medicines Alliances considers that the above challenges should be addressed in priority in a future Critical Medicines Act, while other policy instruments should be developed to address non legislative challenges. In any event, the relevant policy instruments should respond to the general objectives of:

1) Ensuring access to Critical Medicines for EU citizens, i.e. strengthening Critical Medicines supply chains to reduce the risk of shortages in Member States ensuring health security for the continent

[9] Grumiller, J & Grohs, H (2021): Improving security of supply for critical products in the Global North and South post-COVID19: the cases of medical and pharmaceutical goods

[10] E.g. the Advancy report presented to the Alliance WG plenary clearly shows that China and India alone represent a share of 55% of the global production of APIs. The EU represent 30%, and the US 10%.

2) Improving competitiveness of EU industry and ensuring open strategic autonomy

This Strategic Report puts forward a first set of recommendations of the Critical Medicines Alliance for the consideration of the Commission, Member States (whether at national, regional or local level) and/or the industry.

These recommendations are built around the following 3 key specific objectives:

1) Reinforce manufacturing capacity in the EU and ensure its competitiveness on the basis of a solid business case;
2) Support and incentivise the diversification of the production of APIs and/or critical intermediates where there are dependencies on a limited number of third countries and strengthen supply chains via strategic partnerships with third countries;
3) Improve supply and production conditions within the EU by promoting local, sustainable and resilient production along the value chain. This includes strengthening the production of critical raw materials, APIs and medicines.

An overarching objective is the need for enhanced coordination between relevant stakeholders, Member States and the EU as no single entity can solve these challenges alone.

This report may distinguish in certain cases between (i) main recommendations (providing the main actions and objectives to achieve) and (ii) specific recommendations (with specific actions and elements for dedicated targets and objectives). The latter therefore aim to give a more detailed understanding of the steps required to implement the main recommendation.

I. Assess vulnerabilities in the industrial supply chains of Critical Medicines.

Main Recommendation:

- **The Alliance recommends the establishment of a European list of Critical Vulnerable Medicines based on an assessment of structural vulnerabilities within their industrial supply chains (preliminary draft list by mid-2025) (the "Vulnerability Assessment").**

The European Union List of Critical Medicines was put forward by the European Medicines Agency (EMA) in December 2023 to help combat shortages of medicines. This is a list of medicines where continued supply is considered a priority for the EU to help health care systems function and avoid serious harm to patients. The Critical Medicines list is compiled based on medical criteria including the severity of the condition, availability of alternatives and additional input from Member States. It is kept updated on a regular basis[11].

However, the vulnerability of the manufacturing and supply of the product is not considered. In April 2024, HERA conducted a pilot exercise to assess the structural and non-structural vulnerabilities of selected medicines' industrial supply chains[12]. Results of this pilot exercise and lessons learned (including data limitations, notably in the absence of the proposed pharmaceutical legislation) led the Alliance to identifying the need to further improve the methodology assessing the vulnerability of products on the list in order to prioritise efforts on those products most in need and to give patient the most benefit. The Alliance considers that such an analysis of industrial vulnerabilities should result in a list of Critical Vulnerable Medicines.

This assessment should be evidence-based in order for the EU to prioritise its policy instruments and financial efforts on manufacturing supply chains for which structural vulnerabilities have been identified.

[11] The Commission has published an updated list on 16 December 2024

Specific recommendations:

- **The Alliance recommends the EU to implement the below-outlined methodology to perform a Vulnerability Assessment of medicines. The aim should be to achieve an actionable list at the earliest time and to conduct periodic updates of the List of Critical Vulnerable Medicines.**
- **The Alliance recommends the EU to maintain involvement of the relevant Alliance stakeholders in the development of the list of Critical Vulnerable Medicines.**

This assessment is **recommended** to be performed on a regular basis on medicines from the Union List of Critical Medicines. This assessment will guide the Commission, Member States and industry in prioritizing targeted actions and direct investments to secure the supply of these critical and vulnerable medicines in the EU.

The Alliance **recommends** a revised methodology for this Vulnerability Assessment (using the outcome and lessons learnt from the pilot exercise conducted by HERA based on adapted DG GROW methodology [13] (see Annex I for full details)), primarily developed to identify vulnerabilities in the supply chains of established critical medicinal products with multiple MAHs/manufacturers and marketed since several years (while noting that there is a need to develop a methodology to cover all Critical Medicines). It involves a new two-step process to comprehensively analyse the vulnerability of Critical Medicines. First, a shortlist of the most vulnerable medicines is created using qualitative indicators. Then, these medicines should undergo further evaluation using a combination of qualitative and quantitative indicators, notably by considering potential vulnerabilities associated with global multinational supply chains and/or environmental, social and safety aspects. Indicators shall be further refined, to set thresholds and weights adapted to the medicine. Additionally, the Alliance suggests exploring predictive analysis models to anticipate future shortages, which could offer valuable insights into supply chain vulnerabilities and the availability of Critical Medicines.

The Alliance **emphasizes** the importance of an iterative approach to maintaining and updating the list of Vulnerable Critical Medicines, with periodic reviews considering changes in supply chains and the pharmaceutical market.

[13] Assessment of the supply chain vulnerabilities for the first tranche of the Union List of Critical Medicines: Technical report - European Commission

The Alliance **recognises** that each medicine has its own specificities and will necessitate a dedicated assessment. This includes the need to consider the difference between off-patent medicines where multiple suppliers may be operating and patent-protected medicines with one supplier. The proposed methodology will need to be further adapted for critical innovative medicinal products where there is a sole MAH/manufacturer.

The Alliance **proposes** for a preliminary draft list of Vulnerable Critical Medicines to be established by mid-2025, with the goal of full implementation by the end of the same year. To meet this objective, interim actions such as conducting Vulnerability Assessments in batches and using temporary Vulnerability Assessment results to prioritize initial actions should be considered. The Alliance recommends conducting this Vulnerability Assessment involving the Alliance stakeholders due to their role in generating and sharing data.

II. Strengthening European manufacturing of Critical Medicines by investing in EU strategic projects

The structural low profitability of mature drugs, mainly off-patent generic drugs, facing intense downward price pressure, along with a growing competitiveness gap with Asian producers of raw materials, intermediaries, and APIs, has led to offshoring and concentration of strategic commodities' production primarily in China and India. Lower production costs and less stringent regulatory standards in India and China have driven the transfer of API production to these countries. The costs of developing, testing, producing and marketing generics in these regions are estimated to be 20-40% of the corresponding cost in Europe[14]. As a result, these countries have become the leading suppliers of pharmaceutical ingredients for essential and generic drugs consumed in Europe, creating a key vulnerability in the supply chain and contributing to recurring tensions and supply shortages.

The geographical concentration of production chains appears as a critical risk factor for supply chain tension and shortages[15], particularly when no viable alternatives exist in Europe[16]. Strong European manufacturing of Critical Medicines offer strategic advantages for Europe, as evidenced during the COVID 19 pandemic. These include security of supply, competitiveness and a stronger EU presence in global healthcare. Implementing effective incentives for investment can bolster these strategic advantages, encouraging pharmaceutical companies to invest and/or reinforce manufacturing. This approach aligns with the EU's industrial policy objectives of fostering a resilient, innovative, and high-quality healthcare sector.

In comparison to innovative medicines, there are limited incentives (through both public or private funds) for investments in mature medicines of the Union List of Critical Medicines, which often rely on older manufacturing processes. As such, a solid and dedicated **strategic project framework** should therefore be established. This should cover projects essential for reinforcing the supply, resilience, and competitiveness of the Critical Medicines industry in the EU.

Strategic projects could be of varied nature but should, in any event, have positive spill-over effects for the security of supply of Critical Medicines in the EU beyond one given Member State and therefore be in the public interest. Beyond their primary objectives, strategic projects should

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[14] While an average Western API company has an average wage index 100, an average Indian API company has 10.

[15] 2019 EAHPS medicine shortages survey

[16] Shukar S, Zahoor F, Hayat K, Saeed A, Gillani AH, Omer S, Hu S, Babar Z-U-D, Fang Y and Yang C (2021) Drug Shortage:
Causes, Impact, and Mitigation Strategies. Front. Pharmacol. 12:693426. doi: 10.3389/fphar.2021.693426

have a positive impact on the industry supply chain and downstream sectors contributing to skills and workforce development and contributing to creating new employment and improving regional dynamics. These projects should be supported by national or regional authorities and enabled accelerated implementation.

Relevance of EU and national funding instruments to strengthen manufacturing capacities in the EU

To assess the relevance of existing EU funding instruments to strengthen manufacturing capacities in the EU, the Alliance conducted an analysis of the existing financial incentives tools in the EU in addressing the identified needs. The Alliance developed a dedicated matrix of relevant EU programmes and State Aid tools matched against areas most vulnerable to global supply chain disruptions.

Several needs that should be prioritized for support have been identified through this work:

- **APIs and intermediates** were identified as the most common vulnerable components of the supply chain, for which public support appears utterly important. If the appropriate tools or intervention's rate might be different, finished products need to be in the perimeter of an investment plan to guarantee continuity in the value chain.
- **In terms of types of expenditures:**
    - **Infrastructure and CAPEX** investment support has been identified as the top priorities, particularly investing in modernization and greener production technologies, and enhancing process efficiency, notably – but not only - in the manufacture of Active Pharmaceutical Ingredients (a typical project would be between 5 to 20 M€[17] depending on the complexity of the product).
    - **Targeted research and development** (R&D) could help to drive process efficiencies and maintain competitiveness in the sector with an improved environmental footprint.
    - **OPEX could be relevant in some precise cases**, mainly in the first deployment years (in link to test batches and ramp-up of the production).
    - **Skills development** for maintaining production efficiency, especially during scale-up phases, and for ensuring the high-quality standards needed in pharmaceutical manufacturing.

[17] This range was defined during technical subgroup meetings with members of the alliance when asked about the conditions for creating a sustainable business case of API production in Europe.

The Critical Medicines Act should also support investment in the digitalisation (Industry 4.0) of the off-patent manufacturing sector in Europe (both API and FDF production). This would enable greater efficiency and resilience in production and reduce the labour cost and compliance cost advantage of Asian competitors. This would also reduce shortages by increasing the flexibility and efficiency of manufacturing processes to better respond to the highly volatile nature of demand for medicines on the EU market

It was suggested for financial incentives to prioritize projects that **integrate multiple tiers of the pharmaceutical supply chain** (e.g., intermediates, APIs, Finished Dosage Forms (FDFs)) to strengthen supply chain resilience and flexibility.

In addition, future investments must allow for holistic and flexible support, acknowledging that Europe's pharmaceutical industrial base of Critical Medicines comprises both SMEs and large groups that need to invest, regardless of their location in the EU. This approach ensures equitable access to support and fosters an inclusive and balanced industrial strategy.

To address these needs, the Alliance proposes several action points, **under an ambitious and robust European Investment Plan**, to strengthen production capacities for Critical Medicines in Europe.

The need for a coordinated European Investment Plan

Recommendation:

- **The Alliance emphasizes the need for an ambitious European investment plan to strengthen production capacities for Critical Medicines in Europe, and for ensuring an EU-level coordinated approach to implement it**

As no existing tool is currently directly matching the expressed need, in particular for mature medicines, the EU (i) should implement short-term modifications to existing EU and national financing tools to reduce approval times and increase responsiveness and (ii) create a dedicated investment programme for Critical Medicines in the medium to long-term.

A dedicated investment programme for critical medicine production, combined with a tailored funding framework, could provide a suitable solution. This programme would establish clear criteria for public support, and operate as a one-stop-shop under a tailored aid regime and/or an EU funding framework.

This European investment plan must be coordinated at the EU level to ensure consistency, efficiency, and alignment with strategic objectives. This coordination should be underpinned by rigorous scope definition and clear commitments from beneficiaries to deliver tangible results that enhance the EU's pharmaceutical resilience and strategic autonomy.

The recommended European investment plan must adopt a coordinated, holistic, and differentiated approach to address the diverse risks associated with Critical Medicines. The Vulnerability Assessment long-term planning and strategic vision will play a pivotal role in identifying critical and vulnerable medicines requiring public support to foster European production capacity. Regularly updated data from the Vulnerability Assessment will also help pinpoint the weakest links in the supply chain, guiding a well-coordinated European policy.

To strengthen supply chain resilience and flexibility, financial incentives should prioritize projects that integrate multiple tiers of the pharmaceutical supply chain, such as intermediates, APIs, FDFs. These efforts will ensure continuity in the supply chain and support the establishment of industrial consortia of industrial sites strategically distributed across the EU, encompassing diverse regions and Member States.

A strategic, unified, and long-term vision focused on EU strategic autonomy was largely underscored. Reducing long-term reliance on external suppliers will require developing robust internal capacities for essential pharmaceutical manufacturing. This vision necessitates **EU-level cooperation and coordination, including with civil society, to prevent competition distortions among Member States and promote cohesive and coordinated response**. **Dedicated governance structure,** aligned with the implementation of the Vulnerability Assessment, will be critical to ensuring this cooperation.

The Alliance recommends that any new tools, which are to be developed at EU level, should also be adapted to the use and benefit of all undertakings, in particular SMEs.

Effective implementation will require strong alignment between various levers recommended by the Alliance, including public procurement, level-playing field measures, trade protection mechanisms (when necessary), and developing the right framework conditions to make relocation efforts sustainable in the long-term. While measures to relocate the production of APIs, finished medicines, and health products can yield medium-term successes, long-term sustainability will hinge on public demand incentives and policies that ensure fair competition. These measures are crucial for maintaining commercial viability and preventing a resurgence of dependency on cheaper imports from Asia.

Financial support provided under this plan must be accompanied by firm and proportionate commitments from beneficiaries, such as prioritizing the supply of the European market during periods of supply tension. The Alliance underscores the importance of an ambitious investment plan designed to enhance European sanitary sovereignty and secure the supply of Critical Medicines for the benefit of European patients.

This integrated and forward-looking approach will lay the groundwork for a resilient and strategically autonomous pharmaceutical ecosystem in Europe.

A. Financial Incentives at EU level for strengthening Critical Medicines production

Main recommendation:

- **The Alliance recommends that the European investment plan rely on the combination of an EU funding programme and a state aid regulation allowing to support capacity projects in the scope of Critical Medicines.**

a. EU funding programmes

Specific recommendation:

- **The Alliance recommends the creation of a Critical Medicines production-specific one-stop-shop, under an EU funding programme dedicated to production of APIs and essential medicines.**

Existing EU funding programmes under MFF 2021-2027 (Horizon Europe, EU4Health, European Regional Development Fund) offer incentive financing solutions. Their current focus on innovation and greening projects[18] limits their application for mature medicines and some of the needs identified above.

A Critical Medicines production-specific **one-stop-shop** under an EU funding programme could offer a solution to develop/ de-risk industrial infrastructure for producing APIs and Critical Medicines so as to ensure security of supply in the EU. Such an initiative could be put forward as part of the negotiations on the revision of the EU multi-annual financial framework (MFF).

This financial support should be accompanied by commitments to supply the European market in the event of tensions on part of the production supported, and public authorities should monitor such commitments.

[18] i.e., Activities aiming at establishing new knowledge or to explore the feasibility of a new or improved technology, product, process, service or solution

The Strategic Technologies for Europe Platform (STEP) was introduced under the current MFF to boost investments in critical technologies and products in Europe, either to promote innovation or to prevent the Union's strategic dependencies, including in Critical Medicines and their components, as listed on the Union List of Critical Medicines. The STEP seeks to reinforce and leverage existing EU instruments for a quick deployment of financial support for the development or manufacturing in the Union of critical technologies and products in several fields. STEP projects can be supported through several programmes, such as cohesion policy programmes, EU4Health, Horizon Europe or InvestEU.

A complementary STEP Seal (Sovereignty Seal), applicable also to Critical Medicines, could grant projects visibility and facilitating their access to other possible sources of funding.

b. Private funding

Specific recommendation:

- **The Alliance recommends that public financing tools should be strategically coordinated with the EIB, multilateral banks and private sector banks, to improve access to private finance for high-risk projects.**

The EIB, for example, can provide financing for different areas of pharmaceutical manufacturing, from investing in infrastructure, innovation, digitalisation and technology transfer, to specific medicinal products, devices and diagnostics, and addressing unmet medical needs in cooperation with, notably, patients' representatives and health professionals, through agnostic therapeutic indication. Several investments in pharmaceutical companies have already been done to date by the EIB, making use of the variety of their programmes, such as under Invest EU.

The InvestEU Fund provides a budgetary guarantee to the EIB Group and selected implementing partners, facilitating access to financing for projects that involve higher risk. The programme can provide direct loans to companies and SMEs, equity investments through intermediaries and guarantee instruments for loans provided by the EIB and by the public investment banks of each Member State. Healthcare sector is notably targeted by the Research, Innovation and Digitalisation (RID) window. To support private investment into Critical Medicines, conditions for funding should be adapted to reflect the funding criteria beyond innovation.

B. Financial Incentives at National level for strengthening Critical Medicines production

a. State Aid programmes

Specific recommendations:

- **The Alliance recommends the consideration of a new State Aid regulation, restricted to Critical Medicines, allowing differentiated funding of large groups and SMEs within the EU for production capacity investment projects.**
- **The Alliance recommends the launch of a dedicated IPCEI, in specific cases, when documented evidence suggest a substantial competitivity gain potential from beyond state-of-the-art innovation.**
- **The Alliance recommends the launch of a Critical Medicines SGEI coordinated at EU level to limit the risk of critical shortages, through a compensated public service obligation, in specific cases of products with low market viability.**

Existing tools

State aid, such as direct grants, loans, risk finance investments, and tax advantages, can be compatible with the internal market under specific conditions. These aids can be exempted from notification under the General Block Exemption Regulation (GBER). However, current state aid tools only partially address the identified needs due to limitations in amounts, project types, company sizes, geographical areas, and restrictions on supporting CAPEX and OPEX investments. Ad Hoc notification allows Member States to go beyond the amount limitation to some extent, but it imposes a higher burden on beneficiaries.

Important Project of Common European Interest (IPCEI) is a state aid instrument included in Article 107 (3) (b) TFEU and concretized in the European Commission's IPCEI Communication of 2021. It focuses on breakthrough innovation beyond the global state of the art. The first wave of the IPCEI on health (Med4Cure), authorized by the European Commission in May 2024, emphasizes process innovation that can be a significant competitiveness lever but is only part of the solution for strengthening manufacturing capacities and raw material suppliers of Critical Medicines in Europe.

Recommended evolutions

To modernize, where relevant, the manufacturing base for API and Critical Medicines in the EU, the Alliance suggests reviewing and updating the below-detailed state aid tools to provide more flexibility in addressing security of supply and strategic autonomy challenges, while maintaining the level playing field principle in the Internal Market.

In the short term, a new State Aid regulation, limited to a list of Critical Medicines, could fund large undertakings and SMEs without geographical restrictions. It would feature differentiated aid rates, supporting production capacity investment projects, including an optional innovation and greening premium. This State Aid regulation could be complemented by a mechanism ensuring consistent EU strategy and coordination in project selection.

State Aid under a new framework

A new framework could be a strong remedy for Critical Medicines production capacities, addressing the new challenges of competitiveness and dependency on foreign imports the EU is facing, and opening funding perspectives to both large undertakings and SMEs. Such a new framework could be part of the Clean Industrial Deal and would not only allow Members States to support the green transition but would also allow support to modernize existing and new production capacity in strategic sectors, to work towards the EU's strategic autonomy.

Such a framework, in line with the recommendations of the Draghi report, could be implemented as of the second semester of 2025 and include certain limitations to prevent any distortion of competition within the internal market (commitments such as an obligation to give priority to supplying European value chains in times of crisis, encouraging recourse to European funds or the use of certain forms of non-subsidized aid ...).

Important Project of Common European Interest (IPCEI)

An IPCEI could be a powerful State aid tool to foster research and industrial deployment of innovative manufacturing processes and technologies, in specific cases, where the process is the limiting factor, and when documented evidence suggests a substantial competitivity gain potential from innovation.

In the field of Critical Medicines, taking into consideration the experience gathered so far from Alliance members in relation to their participation to IPCEI in the health sector, the Alliance members consider that the IPCEI State aid instrument is less adapted to SMEs and to manufacturers producing well-established medicines or APIs, as it mainly focuses on innovation (and is not suitable for support to production capacities) and that it involves a complex legal framework and represents a significant administrative burden for the companies involved in its implementation.

Service of general economic interest (SGEI)

Services of general economic interest (SGEI) allow a Member State to finance a mission of general interest involving a public service obligation (that could be defined through a company's commitment to make its production capacity available to Europe in the event of a failure to supply the value chains, in the case of Critical Medicines), for the benefit of citizens or in the interests of society as a whole. This tool implements a compensation mechanism, defined in the regulations, whose potential to finance certain projects needs to be assessed.

It seems that this tool could be particularly relevant in some specific cases of products with a structural low market viability (small volumes, crisis products) and thus be more adapted to keeping some Critical Medicines on the market rather than fostering relocation projects. To reach

a level of incentive effect sufficient to foster relocation projects, it would be necessary to couple it with a public support on the investment and would imply that the rules for calculating compensation should be easy to cumulate with state aids and European funding.

The introduction, in the context of specific Critical Medicines, of a coordinated SGEI at EU level to limit the risk of critical shortages at EU level, mentioned by the Commission in its Communication on addressing shortages of medicines of October 2023, should still be explored and would require a review of the Decision and Framework governing the SGEI, as well as a coordination mechanism for several MS to participate.

b. Proportionality of public funding and preservation of the single market

Specific recommendation:

- **The Alliance recommends Member States to earmark parts of the shared management European funds to contribute to the objectives of the CMA.**

The purpose of the Alliance's recommendations is to guarantee the production of Critical Medicines in Europe and to ensure their availability to the European population in the event of a crisis. Therefore, public funding (European funds and aid from Member States) granted to companies should be strictly necessary for these objectives and proportionate to the financing needs of companies including the private part of investment from the undertakings and from the financial market actors.

Shared management funds, such as the European Regional Development Fund (ERDF) or the Cohesion Fund (CF), are run by the European Commission and national authorities in the Member States together. The national administrations are responsible for choosing projects to finance and take responsibility for their management, with the Commission making sure of the successful conclusion of the projects.

It appears essential that a share of European funds managed by Member States can be earmarked for the objectives of the Alliance, in order to avoid excessive disparities in the means of action among Member States, thereby also making sure funds are used in an optimal way and not creating overcapacity for one critical medicine, while at the same time impeding funding for other Critical Medicines or technologies In this perspective, it therefore appears necessary that the rules for cumulation between the different European funds and State aid be applied in a simple and uniform manner.

c. Skills

Specific recommendation:

- **The Alliance supports a coordinated approach to skills development to address immediate workforce shortages and ensure long-term sustainability and competitiveness within the sector.**

The Alliance identified the scarcity of skilled manufacturing workforces as a critical issue, particularly in highly competitive employment areas. Addressing this challenge requires targeted initiatives to develop and sustain a workforce with specialized training in pharmaceutical manufacturing. 4 European programmes have been identified by the Alliance as key opportunities. They include the European Social Fund Plus (ESF+), Horizon Europe, Erasmus+ and the Digital Europe Programme.

To address skills gaps in the European health industries, DG EMPL launched the Pact for Skills under ESF+. This initiative brings together stakeholders from the pharmaceutical industry, academic institutions, and other ecosystem partners to form a large-scale skills partnership. Coordinated by EIT Health, this partnership is designed to expand training opportunities across Europe. Key objectives of the partnership include:

1. Improving Skills Intelligence: Monitoring industry needs and identifying gaps in workforce capabilities.

2. Designing Aligned Training Programmes: Developing curricula that match current and future industry requirements.

3. Drafting a Comprehensive Skills Strategy: Creating a cohesive approach to ensure that healthcare professionals and organisations are equipped to meet emerging challenges.

By leveraging these European programmes and initiatives, the Partnership aims to create a robust pipeline of skilled professionals to support the pharmaceutical industry's growth and resilience. A coordinated approach to skills development will not only address immediate workforce shortages but also ensure long-term sustainability and competitiveness within the sector.

III. Ensuring the security of supply of Critical Medicines through updated contingency stocks and procurement strategies

a. Strengthen EU solidarity through contingency stock

Recommendation:

- **The Alliance recommends the industry, Member States and/or the EU to implement a comprehensive harmonised and balanced framework on contingency stocks to be defined in the Critical Medicines Act.**

Building on already existing mechanisms, such as the voluntary solidarity mechanism under the MSSG, the Alliance is supportive of a European approach to ensure that Member States are not competing over supplies and can rely on EU solidarity when faced with shortages. This includes the question of contingency stocks requirements which, while broader in their scope than Critical Medicines, may impact their security of supply.

To mitigate the risk of shortages, several Member States have implemented **contingency stock obligations**, which mainly require suppliers to maintain national reserves of Critical Medicines. These **mandated supplier stocks** are regulated by authorities but remain under the ownership of suppliers. However, these stocks are typically reserved for a single country, hindering the equitable distribution of essential medicinal products according to patient needs.

While stocks of medicinal products can help mitigate the impact of supply chain disruptions on health systems, uncoordinated approach within the EU can lead to **misallocation of products**, particularly for medicinal products already at high risk of shortages due to market concentration. As a result, patients may increasingly experience disruptions to their health care due to further strain on supply chains, which may prevent from efficiently addressing shortages and undermine the principle of solidarity, as stocks are restricted to national markets. Furthermore, excessive contingency stocks increase the likelihood of stock write-offs, which is both wasteful and financially burdensome. Excessive and uncoordinated contingency stocks can also exacerbate market consolidation, as it places additional pressures on already strained generic medicine markets and supply chains.

Current level of coordination among Member States regarding contingency stock shall improve. Unilateral national stocks fragment the market and negatively impact the patients´ access to medicinal products, as some countries might hoard supplies, worsening shortages elsewhere and increasing health inequalities and tensions between Member States. While committees such as the EMA's Medicines Shortages Single Point of Contact Working Party and the MSSG provide essential technical oversight, there is a pressing **need for enhanced strategic coordination at the EU level**.

A clear framework covering both national and EU contingency stocks is needed to mitigate the potential negative consequences of current national contingency stocks. It is also important to facilitate the reallocation of stocked medicinal products to Member States in case of shortage, ensuring that solidarity mechanisms are effective, and Member States have mechanisms that allow them to share the stock in time of need. Additionally, although contingency stocks may be created by each Member State, such conditions should never put patients' lives and the primary availability of medicinal products at risk.

Therefore, the Critical Medicines Alliance proposes the below specific recommendations. Although these recommendations apply primarily to the Union List of Critical Medicines, it is appropriate to apply them to any measures and obligations related to contingency stock of critical medicinal products[19]at the Member State level or EU level.

Beyond that, the Alliance realises that root causes of shortages for different product groups are multi-factorial and, therefore, contingency stocks of medicinal products do not address root causes of supply disruptions and shortages, and such measures cannot be used as a one-size-fits all solution. The need for contingency stocks should be assessed in the broader supply ecosystem recognising the shared responsibility with other supply stakeholders and should be proportionate to the identified risks. Additional measures to ensure EU resilience of supply of medicinal products are needed, especially rules supporting EU production capacities of critical medicinal products.

The framework on contingency stock can be also coordinated with the framework on public procurement of medicinal products. In this case, it should be accompanied with a more overarching public procurement strategy.

The recommendations put forward to Member States and/or the EU, and industry where relevant (later referred to as targeted parties) apply to:

- mandated **supplier contingency stock**, when there is a requirement imposed by an authority (such as a government or regulatory body), but the responsibility for maintaining and owning the stock remains with the supplier, and
- **contingency stock done, managed and controlled by the Member States or EU** related to supply chain disruptions and the prevention of shortages of medicinal products (strategic reserves of Member States or EU intended for use during emergencies, such as health threats, natural disasters, economic crises, are excluded),

These should be considered without limiting the phase of the product (unfinished or finished medicinal product) that is stocked, the ownership of the stocked product or the existence of financial compensation for holding and managing the contingency stock.

[19] A critical medicinal product is a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients.

Based on the current set of obligations related to contingency stocks in many Member States, the Alliance acknowledges that it would be uneasy and maybe even impossible to reset the system from point zero. For this purpose, it is needed to combine balanced and proportionate obligations related to national contingency stock, EU contingency stock and contingency stock of unfinished medicinal products based on an impact assessment and relative to lead (response) time.

The implementation of such a framework on contingency stocks should consider the following specific recommendations.

Forecast and data analysis to ensure proportionality of required stock

Specific recommendations:

- **The Alliance recommends targeted parties to evaluate relevant data connected to manufacturing and storage capacities and use forecasting, when implementing contingency stock obligations to ensure proportionality.**

Before setting an obligation to stock medicinal products, it is important to evaluate relevant data connected to manufacturing and storage capacities and the ability of suppliers to prevent disruptions of planned production and supplies during the uptake of stock. Based on such evaluation, it might also be needed to approach some categories of medicinal products or entities differently than others (e.g. seasonal medicinal products, orphan medicinal products, paediatric medicinal products; hospital pharmacies, community pharmacies). Additionally, also a targeted time period for restocking of the medicinal product after covering a supply disruption or shortage should be set by the Member States according to the possibilities and capacities of the market, while taking into account that these circumstances may vary strongly and, thus, it is not possible to set binding time periods.

When forecasting and setting the amount of obligatory stock, historical data related to supply disruptions and shortages must be considered as well as the criticality of the medicinal product and expected demand (including seasonal variation and demand spikes). Based on experience of interruption of supplies, it is also important to set up measures that avoid unnecessary accumulation of medicinal products in the distribution chain and pharmacies after the recovery from shortage. For this purpose, the Member States must evaluate data related to supply disruptions and shortages, communicate with the marketing authorisation holders and other stakeholders, and use modern technologies that can help with the forecasts. Enhancing supply-demand planning through better data collection and collaboration with institutions like the ECDC and EMA, is critical for ensuring medicinal product security across Europe. By integrating real-

time epidemiological data and other demand indicators[20], a more accurate forecast of medicinal product can be developed. This approach allows for strategic stock allocation, avoiding the pitfalls of both overstocking[21], which leads to waste and can exacerbate shortages, and understocking.

Additionally, assessing whether all countries need to stock the same medicinal products or if demand can be more efficiently distributed across the region is essential. A comprehensive understanding of stock levels throughout the supply chain (supplier, wholesaler, pharmacy/hospital) should precede the final stock arrangements to create a more responsive and resilient system that adjusts to fluctuating demands. Such proactive planning can avoid disproportionate stock and prevent large quantities reserved for a national market shifting supply away from other Member States, hindering patient access and increasing the risk of shortages across the EU. A mechanism should be set in place to prevent unequal distribution of medicinal products from wholesaler to community and hospital pharmacies in case of limited availability of medicinal products and usage of stock to prevent unnecessary unavailability at the level of community pharmacies.

Prevention of waste

Specific recommendation:

- **The Alliance recommends targeted parties to implement stock management strategies to ensure prevention of waste.**

Contingency stocks can increase the risk of generating a considerable waste and consequent destruction of medicinal products, especially for products with a short shelf-life. For antibiotics, destruction may also present an additional risk of antimicrobial resistance (AMR) development. To prevent those negative consequences, the contingency stock system should be regularly renewed on first-in first-out basis and the different expiration time of stocked product (e.g. category of medicinal product) should be considered. It should also be considered that it is easier to set such processes in the environments of marketing authorisation holders or distributors in comparison to separate warehouses, where medicinal products owned by public authorities are stored. Additionally, stability studies to prolong the shelf-life of critical medicinal products could be facilitated to ensure higher availability of medicinal products.

[20] For example significant changes in international and national clinical management guidelines for strained therapeutic areas such as respiratory infections.

[21] For example, according to Technopolis study on shortages, two thirds of shortages were resolved within the first 3 months.

Transparency between Member States and market consolidation

Specific recommendation:

- **The Alliance recommends targeted parties to transparently share data regarding stock requirements and related measures, and to develop a dedicated database.**

Member States need to be informed about regulatory measures on contingency stock taken by other Member States and at the EU level, including requirements on volume and lead time to build the stock. Before adopting such measures, impact on the availability of medicinal products in Member States should be evaluated to ensure a stock requirement that brings benefits to EU patients and does not cause unwanted negative effects. In case of a critical shortage of a critical medicinal product in a certain Member State, other Member States should consider interruption of creation of contingency stocks or release of existing contingency stocks, when legally possible. Beyond that, a consultation process at the EU level could be set up to share best practices between Member States and find effective solutions.

In order to keep a high level of transparency between Member States, a database that would collect up to date information on current Member States and EU stocks should be created, further allowing products to be reallocated to Member States in need in case of supply disruption or shortage, based on the solidarity principle. Such database should include information on the phase of product that is stocked (unfinished/finished medicinal product), type and amount of such product and its availability for other markets (e.g. rules based on ownership of the product) and data on stock usage and waste (per product).

Reallocation flexibility

Specific recommendations:

- **The Alliance recommends for the EU and national regulation to allow reallocation flexibility.**

To reduce supply complexity and foster rapid reallocation of product in stock across Member States, EU and national regulations shall allow reallocation flexibility related to:

- packaging and labelling requirements (e.g. multi-country packs),
- product information (including electronic product information), while maintaining the right for a patient to request a paper product information
- use of unauthorised medicinal products approved according to the same standards of quality, safety, and effectiveness, and
- solidarity mechanism between Member States

In the case of critical medicinal products on the Union List of Critical Medicines, an EU packaging (same for all Member States) should be considered so that such medicinal product could be allocated to a Member State, at any time, allowing a fast supply of needed medicinal product and avoiding administrative burden.

Regulatory flexibilities would specifically facilitate the reallocation of stock for medicinal products authorised under national procedures (around 90% of authorisations of medicinal products in Europe) and avoid, among others, re-packaging. For the case of critical shortage of a critical medicine product, Member States may implement measures that allow price flexibility related to the reallocation of the medicinal product.

The reallocation flexibility is also affected by the public or private sector ownership of the stocked product and related rights and obligations. When setting the regulatory measures, the ownership rights and obligations should be flexible to ensure that the stocked product may be reallocated to a different Member State if needed. Finally, the reallocation of medicinal product should require approval of the involved Member States.

Financial intensity

Specific recommendations:

- **The Alliance recommends for the targeted parties to assess the financial impact of contingency stocks obligations.**

In addition to the impact on the market that was mentioned above, the financial impact of contingency stock obligations on the Member States, EU and the stakeholders should also be assessed. The contingency stock system and the associated financial burden should be set so that the obligations do not exacerbate shortages or lead to market withdrawals. To understand better the potential impact on relevant stakeholders, these should share, upon request, audited data with the competent authorities on their inventory costs as the total share of production costs and other costs associated to contingency stock, which are not considered to be business confidential.

The Member States should set proportionate sanctions related to contingency stock and take into consideration that contingency stocks may need to be consumed to prevent or mitigate a shortage in a given Member State. The stakeholder should notify the competent authority and do its utmost to replenish it as soon as possible.

Re-evaluation

All relevant data mentioned above should be re-evaluated regularly, after imposing the contingency stock obligations together with the data on the actual usage of the stock, in order to reconsider and tailor stock obligations to actual needs over time.

National contingency stock or EU contingency stock

Specific recommendations:

- **The Alliance recommends the prioritisation of EU contingency stocks for medicinal products with low consumption (such as orphans or innovative antibiotics) or with limited national contingency stocks obligations based on the agreement of the Member States**

Currently, there are national contingency stock obligations in many Member States that are not harmonised and may have negative impact on markets of different Member States and availability of medicinal products for patients. The contingency stock system in the EU should prevent such unwanted consequences and bring benefit to patients in all Member States. To this end, the national contingency stocks and EU contingency stock may work concurrently, while considering the EU's general principle of solidarity, all the general principles stated above and avoiding duplicating contingency stock of the same product.

The EU contingency stock could be beneficial in case of specific medicinal products (such as medicines that were purchased through the EU procurement scheme, orphan medicinal products, or innovative antibiotics) or if there would be a wide reduction of national contingency stock obligations in the future. The positives EU contingency stock brings is the higher transparency of stock and a fast reallocation flexibility enabled by conditions supporting reduced lead (response) times, such as EU packaging. Additionally, there would be a need to establish a predictable system, according to which medicinal products would be allocated between Member States.

Contingency stock of unfinished medicinal product

Specific recommendations:

- **The Alliance recommends the targeted parties to consider contingency stocks of unfinished medicinal products and relevant applicable obligations.**

Contingency stock of unfinished or primary packaged medicinal product allows high reallocation flexibility and supports the prevention of waste, while maintaining patient safety. The impact assessment, in such case, should focus on the phase of the unfinished medicinal product, in which it should be stocked, to bring the most positive benefit on the availability of the finished medicinal product. In such case, appropriate preparatory measures that enable a timely availability of the finished medicinal product, should be implemented. Contingency stock of

unfinished medicinal product does not resolve the immediate unavailability of medicinal product for patients and should be combined with minimum stock of finished medicinal product at Member State level.

An obligation to stock unfinished medicinal product may be also set as a general EU-wide obligation for all marketing authorisation holders (excluding certain specific cases, such as e.g. radiopharmaceuticals), to ease the situation in case of supply disruptions or shortages of medicinal products and allow Member States to resolve such situation or ensure that it affects the treatment of patients as little as possible. This obligation could also reduce national contingency stock measurers related to finished medicinal products as it would ensure higher security of supply of medicinal products.

b. Update of public procurement criteria

Recommendation:

- **The Alliance recommends the EU to promote virtuous public procurement practices within the scope of the Critical Medicines through the systematic integration of essential procurement criteria like supply security, resilience, and environmental impact.**

Procurement of medicines is a national competence, whether in the realm of pricing and reimbursement or the definition *per se* of procurement criteria. EU procurement legislation gives the Member States a large margin of manoeuvre in setting up the criteria for their tenders for the supply of Critical Medicines.

Current procurement practices by Member States – with a particular focus on price as the most important, or even the only meaningful procurement criterion – have been a significant driver of the current market dynamics for mature medicines. These market dynamics have led to consolidation of suppliers and outsourcing to other jurisdictions outside the EU, of all or part of the manufacturing supply chains.

Improving these procurement practices, towards a 'MEAT criteria approach', could change the above market dynamics. This could create powerful incentives for the provision of more sustainable and securely supplied Critical Medicines and would be one of the most effective ways to improve the EU's security of supply in a structural, long-term fashion.

In parallel, EU-wide mechanisms could be used to develop **demand signalling** for more sustainable and securely supplied Critical Medicines.

Manufacturers considering investment in the EU need to know that there will be a minimum demand (volume and price point) for the products that they will produce.

From 'price only' to the use of essential qualitative criteria

According to recent reports[22], over 90% of all reported shortages of Critical Medicines concern generic medicines, where **competition is primarily driven by price**. According to IQVIA, 2/3 of all generic medicine shortages (critical and essential medicines) are associated with products with few suppliers. However, it is essential to recognise that the issue of supply stability extends beyond generic drugs; non-generic, patent-protected medicines are also susceptible to shortages. Likewise, it is essential to recognise that Critical Medicines are not considered a public good in the context of the World Trade Organization's definition[23].

These medicines face vulnerabilities tied to the **concentration of production capacities**, often outside Europe. The **limited supply chain flexibility** and the **reliance on global imports** amplify these risks, especially when disruptions or geopolitical challenges arise.

According to the Public Procurement Directive 2014/24/EU, contracts should be awarded to the Most Economically Advantageous Tender (MEAT), which allows several (including non-price) criteria to be used together. While this approach comes into increasing use, as reported in the study on best practices in public procurement conducted by the European Commission[24] (2022), it currently still accounts for a minority of public procurement procedures (24% of countries), and most are awarded based on price only (62% of countries). Environmental criteria are not yet widely used, but there is experience in some countries (e.g. the Nordic countries in both national and joint tenders).

To address these issues effectively, **public procurement criteria should integrate MEAT standards**, focusing not only on price but also on essential criteria like supply security, resilience, and environmental impact. This will entail fostering market incentives and support measures that encourage the adoption of modern, resilient manufacturing processes. In addition to safeguarding supply chains, these measures can mitigate environmental impacts and ensure a high-quality, continuous supply of Critical Medicines, thus enhancing Europe's autonomy and responsiveness to future public health needs, ultimately improving the availability of Critical

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[22] Vogler S, Fischer S. How to address medicines shortages: findings from a cross-sectional study of 24 countries. Health Policy. 2020; Chapman, S., G. Dedet and R. Lopert (2022), "Shortages of medicines in OECD countries", OECD Health Working Papers, No. 137, OECD Publishing, Paris, https://doi.org/10.1787/b5d9e15d-en.

[23] A public good in the context of the World Trade Organization (WTO) refers to a product or service that benefits not only the individual or firm that acquires or produces it but also society as a whole. It is non-excludable, meaning that it is difficult or impossible to prevent others from enjoying its benefits, and non-rivalrous, meaning that one person's consumption does not diminish the availability for others. Examples of public goods in the WTO context include public health measures, environmental protection, and public infrastructure. These goods are subject to international trade rules, which aim to promote fair competition, remove trade barriers, and foster economic growth among WTO member countries.

Medicines for patients. **By rewarding positive externalities associated for instance with the production in the EU of active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs), the inclusion of security of supply, resilience and environmental criteria will also be a strong lever to improve the competitiveness of the European industry, in a consistent approach with the other recommendations of the Alliance.**

To this end, several levers can be effectively mobilised in public procurement:

- **Eligibility Criteria**: Defining minimum requirements that must be met for tender eligibility;
- **Award Criteria**: Encouraging sustainability, security of supply, and resilience through specific award criteria;
- **Performance Clauses**: Including execution clauses that progressively enhance transparency and security of supply;
- **Multi-Award**: Implementing multi-award strategies to ensure resilience and diversification in procurement.

Specific recommendations:

- **The Alliance recommends the systematic application of specific MEAT criteria in Critical Medicines public procurement in the EU, to be covered by the Critical Medicines Act.**
- **The Alliance recommends for the Critical Medicines Act to promote public procurement practices that reward the security of supply granted notably by EU-production and contributing to sustainable markets; an appropriate legislative instrument that ensures legal certainty and uniform application of the criteria in the EU should be identified by the Commission; in addition, an implementing act should be adopted providing guidelines on the application of each criterion.**
- **The Alliance recommends the EU to implement a mechanism prescribing specific selection criteria and weighting ranges in tender evaluations.**

More specifically, the Critical Medicines Act should cover the application of the specific MEAT criteria in Critical Medicines public procurement in the EU (definition, weighting, eligibility or attribution for each criterion). The Act should also define the exemptions and flexibilities.

An implementing act to be adopted should include sufficiently precise guidelines on how to apply each criterion to enable Member States to apply the framework without risk of legal consequences (e.g.: method of application for each criterion, minimum data requirements); and to secure supply of Critical Medicines.

Such an act will avoid fragmentation, while allowing Member States the flexibility to adapt implementation at the national level, especially when tackling potential contract clauses and penalties that should not lead to companies withdrawing from the market, (especially considering the heterogeneity of national systems).

Scope of application

The approach outlined applies to medicines listed in the **Union List of Critical Medicines** and identified as vulnerable as through the established Vulnerable Critical Medicines list on the basis of the vulnerability assessment. Additional Critical Medicines may subsequently be included as their critical status is recognised.

Method and objective

The success of the framework depends on its capacity to generate **viable industrial bids** for public buyers avoiding as much as possible impact on affordability. Establishing a mechanism that prescribes specific selection criteria and their weighting in tender evaluations would help achieve this goal.

This approach should rely on a **limited set of measurable metrics**, **enabling transparent data-driven evaluations** and **clear, enforceable standards,** designed to promote long-term improvements and the standardisation of criteria across the sector.

Public procurement rules

Contracting authorities should base the award of contracts for Critical Medicines on the most economically advantageous tender, which shall include the best price-quality ratio, comprising at least of three criteria: environmental, security of supply and resilience criterion. A well-balanced minimal weight per criterion that should be defined at EU level (see Annex II). Furthermore, the following considerations should be taken into account in public procurement processes:

- Increase demand predictability, when designing tenders, authorities should ensure sufficient lead time and provide realistic volume estimates, along with commitments and guarantees for Critical Medicines supply;
- If appropriate, calls for tender should allow for the selection of multiple suppliers to diversify stakeholders and thereby contribute to supply security;
- All public procurement criteria should be objective, transparent, non-discriminatory and in line with the EU international commitments;
- For contracts covered by the Union's Appendix I to the World Trade Organisation Agreement on Government Procurement (GPA) or by other relevant international agreements by which the Union is bound, contracting authorities and contracting entities should not apply those requirements;
- Exemptions should be applied for:
    - Critical Medicines that can only be supplied by a specific operator, with no reasonable alternative,

- previous procurement procedures (within two years) yielded no suitable offers,
- situations where the application of the requirements would lead to excessive costs (threshold to be defined) or technical incompatibilities in the healthcare system, where significant cost differences may be presumed to be disproportionate[25];

- Coordination efforts between the European Commission and Member States is important to ensure consistency and clarity in applying those criteria in public procurement for Critical Medicines. It also involves sharing best practices between Member States (through the production of guidelines on application of above-mentioned criteria, adoption of an implementing act and establishment of a platform for best practices sharing).

c. Updated Joint Procurement approach

Specific recommendation:

- **The Alliance recommends making use of Joint Procurement as a way to address the fragmentation of the market and to update the Joint Procurement Agreement's scope to tackle shortages of medicines.**

The Alliance considers that in some circumstances, the fragmentation of the EU Internal Market may negatively impact the predictability needed for further investment in manufacturing and in resilient supply chains, which in turn reduces security of supply. This may be the case, for example, for some smaller volume medicines where there is insufficient volume in some Member States for a commercially viable market.

Joint Procurement between Member States (at EU level or regional level in a decentralised manner) on a voluntary basis can contribute to improve availability, affordability and security of supply of Critical Medicines, by strengthening the negotiating position of Member States, but also allowing for a stronger reliance on MEAT criteria to ensure overall positive effects on the supply chain. Joint Procurement can also improve demand signalling to incentivise production capacities. Joint procurement should ensure that there is no disruption to pre-existing (national or regional) contracts and participating Member States should not tender nationally/locally for the same medicines for the duration of the European or regional joint tender. Competing joint and national procurement would generate shortages as manufacturers would need to produce for both tenders without knowing which one takes precedence. In order for this joint procurement to be cost-effective from a public health perspective we need to ensure that: (i) there are objective criteria in place for establishing its scope, also relying on transparent and detailed

[25] This provision does not prejudice the possibility of excluding abnormally low bids, according to article 69 of Directive 2014/24/EU. The article prohibits any form of discrimination or unjustified different treatment between suppliers from different EU Member States, ensuring that all suppliers are treated equally in procurement processes.

information about current stocks within the EU, (ii) that it does not distort the internal market and (iii) that price-setting is based on a methodology jointly established with the member states participating.

EU-level policy tools and instruments should be updated to tackle these changes. For example, joint procurement could be used to identify and consolidate demand from Member States for critical and life-saving medicines. This may require an adaptation of the EU Joint procurement mandate to include the prevention of shortages or unavailability in several member states, using the Critical Medicines Act as a new legal base to extend the scope of the Joint Procurement Agreement at least to Critical Medicines with the application of MEAT criteria to the JPA within its scope.

For larger volume joint procurement, for example for crisis preparedness, procurers should consider multi-award tenders as this reduces pressure for industrial consolidation which is the root cause of medicine shortages and supply dependency.

IV. Fostering a level-playing-field for Critical Medicines production

Recommendation:

- **The Alliance recommends for the EU to promote a level playing field, concerning environmental and social standards but also fair competition between Critical Medicines manufactured in the EU and in the rest of the world.**

Ensuring a fair level-playing field between the EU and the rest of the world, where relevant could create new incentives for the production of Critical Medicines. The Alliance has identified various factors related to manufacturing that can impact the competitiveness of EU-based production of Critical Medicines and their APIs within the EU.

In parallel, within the EU, due to diverse national laws and practices (e.g., priority status for strategic projects in permitting procedures, assistance on access to financing, and public procurement criteria), EU member states have significant flexibility to incentivize production and investment. However, varying levels of implementation could create uncertainty for investors and the industry, leading to an uneven playing field within the EU.

Manufacturing in the EU adheres to strict environmental and social standards, while certain non-EU countries may not be held to the same standards. This can have a dual effect: Firstly, it unintentionally externalizes some of the environmental or social costs of medicine production for the EU. Secondly, EU-based manufacturers face compliance costs related to these regulatory standards that non-EU-based manufacturers might not face, which diminishes their

competitiveness[26]. Additionally, non-EU-based manufacturers may receive support from their local or national governments through mechanisms that the Alliance believes may constitute direct or indirect state aid, potentially leading to unfair trade practices.

In order to gather further evidence, the CMA recommends the Commission to undertake a study to identify the sources of competitive disadvantage for EU manufacturers of Critical Medicines, of critical APIs, and of their starting materials, including EU legislation and its cumulative impact. The Commission should also assess if the EU rules on procurement are fully respected for medicines– notably the Guidance on the Participation of Third Country Bidders.[27]

Based on the outcome of the study, the Critical Medicines Alliance recommends that the Critical Medicines Act and its aligned strategy should reflect the situation inside the EU and simultaneously work to establish a level playing field, by fostering fair competition between Critical Medicines produced within and outside of the European Union.

Rewarding the environmental quality of EU-production

Specific recommendations:

- **The Alliance recommends the EU to promote environmentally virtuous products manufactured in the EU, through the introduction of environmental criteria in public tenders. More globally, the EU should work to create a fair and equitable environment for the development and production of Critical Medicines by identifying, promoting and rewarding best practices. To address the level-playing field, the EU should introduce measures and tools that will support best manufacturing practices, including EU-based manufacturing of Critical Medicines, while ensuring their affordability.**

The Alliance observed that Critical Medicines produced in the EU (concerning both APIs and FDF) display a high environmental value that is linked to the high environmental standards applicable in the EU, to its low-carbon energetic mix and to the high degree of involvement of manufacturers operating in the EU in the ecologic transition. However, this environmental value is yet not sufficiently rewarded in the way Critical Medicines are bought.

To this extent, the tools and potential solutions discussed, concerning public procurement, will deliver strong preliminary insights regarding ways to promote best practices in public procurement including rewarding stakeholders for resilience, security of supply and

[26] https://efcg.cefic.org/wp-content/uploads/2025/01/Advancy-Sicos-report-extract-protected.pdf
[27] https://single-market-economy.ec.europa.eu/news/new-guidance-participation-third-country-bidders-eu-procurement-market-2019-07-24_en

environmental commitments. The recommendations put forward concerning public procurement should provide part of the solution to valorise best manufacturing practices of Critical Medicines. More specifically, to facilitate and streamline the deployment of this criteria, the EU should consider a step-by-step approach to include environmental criteria in procurement, based on the evolving best practices and scientific development in the sector. This can include the development of a methodology for assessing the carbon footprint of medicines production and encourage purchasers across the EU to progressively roll out such incentives. The Critical Medicines Act may create an expert group to define and regularly update the criteria for use by purchasers.

To complement downstream valorisation through public procurement, additional tools to promote EU-based production and sustainable practices could be mobilized through soft law instruments: new industry manufacturing standards and certifications, product and consumer awareness, CSR and ESG commitments.

Assessing the need to increase specific standards imposed to extra-EU production

Specific recommendations:

The Alliance recommends the Commission to promptly launch a study to:

- **To identify the sources of competitive disadvantage for EU manufacturers.**
- **To provide a comparison of regulatory standards between EU and non-EU and quantify their impact on competitiveness, environmental risk and public health risk**

The CMA recommends the Commission to undertake a study in 2025:

to identify the sources of competitive disadvantage for EU-based manufacturers and suppliers of Critical Medicines, of APIs and of their starting materials, including within existing and possibly proposed EU legislation, and its cumulative impact on the security of supply of Critical Medicines in Europe. The study could also cover the potential issue of divergences of standards for the performance of GMP inspections inside the EU and in certain countries outside of the EU, and also map direct and indirect subsidies and export promotion policies.

- to clarify which regulatory standards are less stringent overseas than in the EU and quantify their impact on competitiveness of manufacturing in the EU, public health risk and environmental risk. This study should also provide an overview of current and upcoming[28]

[28] Such as UWWTD and PFAS

EU environmental standards, which have an impact on the production of Critical Medicines, APIs and their starting materials.

- to identify the most impactful regulatory gaps and relevant tools for the EU to be able to close them including through potential additional standards to be imposed on products manufactured outside of the EU wishing to enter the EU market (for which imbalances are observed and documented).
- To assess how existing and upcoming EU environmental legislation (including the corporate sustainability reporting and due diligence legislation) impact the shift towards more environmentally virtuous production of critical APIs and medicines within and beyond EU.

This study should be launched in Q1 and would have to be completed by the end of 2025.

The following elements should be considered, based on the outcome of the study:

- the Commission could review the measures considered burdensome for EU-based manufacturers and propose a simplification without impacting the quality, safety and efficacy of the Critical Medicines.
- the Commission could impose additional environmental or social standards to products manufactured outside of the EU and commercialized on the EU market, in a specific calendar and through flexible tools that should impose no additional standard to EU-based productions (the objective being level-playing-field) and not put supply chains at risk, while ensuring affordability of Critical Medicines and facilitating monitoring of implementation.

Having in mind the revision of the framework pharmaceutical legislation and, in line with the Strategic Agenda 2024-2029[29], the CMA should promote a business-friendly environment for manufacturing in the EU that will lead to increased efficiency, reduced compliance costs for businesses, bolster global competitiveness, attracting investments and strengthen resilience with a positive impact on the availability of medicines in Member States, while preserving their affordability.

The regulatory asymmetry on environmental and social standards that exists between the EU and some of its biggest competitors in the field of Critical Medicines has a direct impact on (i) **competitiveness**, (ii) **public health risk** (e.g. in the context of antimicrobial resistance) and (iii) **environmental risk**.

If rewarding the environmental quality of production in the EU is a major step that also offers a lot of flexibility, **it might, in some cases, be necessary to bridge the gap between the standards imposed to manufacturing in the EU and the ones imposed on extra-EU manufacturing authorized for commercialization in the EU**; especially if the impact of the asymmetry regarding some criteria is too high, whether concerning competitiveness, public health risk or environmental risk.

[29] https://www.consilium.europa.eu/en/european-council/strategic-agenda-2024-2029/

Trade defence instruments

Specific recommendation:

- **The Alliance recommends the EU to stand firm against unfair trade practices through active monitoring and addressing of unfair trade practices, by making more effective use of Trade Defence Instruments (TDIs) in line with WTO rules, where relevant in the pharmaceutical sector.**

The EU Commission possesses a toolbox of trade defence instruments (TDI), such as anti-dumping, anti-subsidy, and safeguard measures, which can be employed to shield European industries from unfair international competition.

Consideration should be given to how to raise awareness of the proper use of currently available tools among manufacturers of Critical Medicines relying on production in the EU in the context of a fast-increasing number of cases. In particular, in the context of the current trade challenges faced by the pharmaceutical industry, it should be studied how the EU can accelerate its anti-subsidy and anti-dumping procedures, though still being based on objective case-by-case analysis. The Commission should explore ways to facilitate cooperation with European manufacturers on this matter.

While trade defence instruments can be a valuable tool to protect domestic industries, they should not be used to artificially relocate production of Critical Medicines. The analysis must remain objective on a case-by-case basis with the aim of addressing genuine and proven market distortions. TDI's should be employed selectively and in parallel with measures to strengthen domestic production capabilities and ensure a reliable supply of medicines.

V. Enhancing the resilience of the EU's pharmaceutical supply chain through identification and assessment of alternative countries/regions for establishing partnerships

Recommendations:

- **The Alliance recommends the EU to leverage existing partnerships with third countries and to build new ones.**

While the Alliance focuses on strengthening the global competitiveness of the European pharmaceutical sector by stimulating local production in order to safeguard EU's supply security, the EU cannot independently produce all Critical Medicines.

As such, international cooperation and integration of the global pharmaceutical industry is a key determinant in securing Critical Medicines supply. Consequently, strengthening the resilience of the global pharmaceutical supply chain is fundamental. Given the complexity and interconnected nature of today's global supply networks, a collaborative approach emphasising flexibility, adaptability and diversification is essential. In this context, the Alliance explored ways of strengthening strategic international partnerships as a means to diversify international supply chains and enhance security of supply for Critical Medicines and reduce supply disruption risks.

Partnerships with third countries are instrumental in creating a conducive environment and political support system to address supply chain vulnerabilities and strengthen the resilience of Critical Medicines supply. The Alliance recognises that companies will later play a vital role in the industrial policy pillar as an essential component of these partnerships, ensuring tangible action and meaningful impact. The recommendations and subsequent measures should be guided by the supply chain vulnerabilities as identified in the Vulnerability Assessment of Critical Medicines[30]. Relevant measures must be consistent with the work of the Alliance on incentives to strengthen manufacturing, and more specifically with existing production capacities and projected capacities in Europe, so as not to duplicate and undermine efforts contributing to the strengthening of such capacities.

Partnerships with third countries fall into two overarching categories driven by different starting points: 1) to leverage existing partnerships and facilitate existing trade or 2) to intensify or build new partnerships to secure geographic diversification in future. These partnerships are associated with different timescales, with some to be prioritised for short-term action and others associated with medium- or long-term objectives.

[30] https://health.ec.europa.eu/publications/assessment-supply-chain-vulnerabilities-first-tranche-union-list-critical-medicines-technical-report_en"

On this basis, the Alliance recommends pursuing the following types of partnerships with complementary, not mutually exclusive objectives (Annex III A for a detailed description of the partnership types):

- With established trade partner countries to prioritise continuity, security, and resilience in the pharmaceutical supply chain.
- With large producer and spare capacity countries to pragmatically explore ways to work with third countries that (legally commit not to introduce export restrictions) to prevent supply chain disruptions.
- With neighbouring and strategically positioned countries to foster pharmaceutical supply chains that will enhance resilience and diversification.
- With capacity-development countries to identify opportunities to cultivate and expand pharmaceutical production capacity in a mutually beneficial manner.
- Beyond bilateral partnerships, the Alliance should consider and identify the potential avenues for collaboration through existing bilateral and multilateral platforms such as, for example, the OECD, WHO, US-EU TTC, G7, G20 and EU-AU.

The Alliance developed a macro-level framework (see Annex III B) to evaluate countries and regions for establishing potential partnerships (or strengthening existing ones), in order to enhance the resilience and sustainability of EU pharmaceutical supply chains. This work required a list of clearly defined archetypes of potential international partnerships, each with clear objectives and characteristics (see Annex III A).

Specific recommendations:

- **The Alliance recommends the Commission to pursue partnerships with established trade partner countries, large producer and spare capacity countries, neighbouring and strategically positioned countries, and capacity-development countries.**
- **The methodological framework it has developed should serve as a basis to assess the prospects of non-EU countries for different partnerships. Notably it should consider indicators for production capacity, ease of trade, third-country policy and geographical/geopolitical factors.**

The Alliance developed a macro-level framework (see Annex III B) to evaluate countries and regions for establishing potential partnerships (or strengthening existing ones), in order to enhance the resilience and sustainability of EU pharmaceutical supply chains. This work required a list of clearly defined archetypes of potential international partnerships, each with clear objectives and characteristics (see Annex III A).

Specific recommendations:

- **The Alliance recommends using the methodological framework it has developed to assess the prospects of non-EU countries for different partnerships.**
- **The Alliance recommends assessing non-EU countries, based on four categories, including indicators for production capacity, ease of trade, third-country policy and geographical/geopolitical factors.**

The methodological framework is based on the principles of decision theory and composed of different methodological stages (including decision context definition and identification of explicit value criteria). It is meant to act as a decision support tool for the structured and transparent evaluation of different countries/regions in terms of their prospects to form the four types of partnerships. The Alliance recommends assessing non-EU countries based on 18 key criteria falling under the following four categories:

- Production capacity: the ability of pharmaceutical suppliers in a country to be a source of production and exports of relevant pharmaceutical components.
- Ease of trade: the dynamics and efficiency of existing trade as well as related supply chain and trade policies and processes, also considering that partnership could be built on the EU's capacity to export some Critical Medicines and APIs as the EU.
- Third-country policy: the level of alignment with wider standards for production and for protection of employee rights to those recognised by the EU, or where appropriate, internationally.
- Geographical/geopolitical factors: the possible impact of wider political and social context of countries on partnerships.

The application of the methodological framework and its respective components (including collecting the necessary data and eliciting any value preferences required from the decision makers) should take place throughout the course of 2025. The objective is to produce empirical results in relation to countries ranking/ classification/ categorisation to the different types of partnership categories. These findings should inform the future work of the Alliance, which aims at establishing product-specific criteria to identify and evaluate potential manufacturers and suppliers within prioritised countries.[31]

[31] The Alliance will further develop a micro-level assessment to identify, assess and rank alternative companies (including manufacturers and suppliers), to prioritize companies for potential partnerships in view of enhancing the resilience and sustainability of EU's pharmaceutical supply chains.

VI. Routes to establish and expand international solidarity cooperation

Recommendations:

- **The Alliance welcomes the efforts of the MSSG in the developments of a voluntary solidarity mechanism and recommends the MSSG to formalise the possibility for outreach to third-country jurisdictions, as part of the Voluntary Solidarity Mechanism.**
- **The Alliance specifically recommends the MSSG to explore the possibilities for increase of supply to Europe on a temporary basis, including in view of seasonal demand peaks. The Alliance recommends the MSSG to create a dedicated, structured, transparent, and secure repository for information exchange on Member States' experience as regards their respective bilateral relations with international partners when dealing with national shortages.**

Following the Commission Communication "Addressing shortages of medicines in the EU", the Voluntary Solidarity Mechanism (VSM) was launched in October 2023 at the level of the Executive Steering Group of the European Medicines Agency on Shortages and Safety of Medicinal Products (MSSG) to support Member States experiencing critical shortages. It enables EU and European Economic Area (EEA) Member States, where all other possibilities are exhausted, to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages.. However, in a situation where Member States' capacities would not be sufficient to address each other's needs, support from international partners may be sought (and vice versa).

In view of the above, discussions on international solidarity cooperation commenced within the Alliance. Based on an assessment of possible gaps, structural approaches to strengthen international solidarity cooperation were explored, with the objective of being better prepared for Critical Medicines shortages. All recommended actions build upon the existing VSM, and activities already pursued at EU level for international cooperation on medicines shortages. In this context, international solidarity cooperation is understood to serve as a last resort solution in case of critical shortages, to be employed only when the VSM is unable to resolve the shortage at hand and in accordance with applicable EU legislation, thereby ensuring the safety for patients. Further, international solidarity cooperation is understood to serve as a structured approach for short-term supply in response to ad-hoc Critical Medicines shortages in the EU.

Given the activities already pursued by the European Medicines Agency (EMA) and the MSSG, which has already identified international collaboration in its published MSSG Toolkit on recommendations on tackling shortages of medicinal products, the Alliance recommends **the MSSG** to expand, intensify and complement their ongoing work on international solidarity cooperation.

It specifically recommends the MSSG:

1. to consider updating the VSM to specifically reflect and formalise the possibility for outreach to other jurisdictions.
2. to leverage and further formalise existing platforms for international cooperation, as well as exploring a framework for international cooperation outside of existing structures, including collaboration with relevant supply chain players, healthcare professionals and their respective representative bodies. Existing platform which could potentially be leveraged for this purpose is the Drug Shortages Global Regulatory Working Group, an international forum for medicine regulators, the World Health Organization through which regulators already exchange information on Critical Medicines.
3. to create a dedicated, structured, transparent, and secure repository for information exchange on Member States' experience as regards their respective bilateral relations with international partners when dealing with national shortages. In case of an ad-hoc critical medicine shortage, Member State national competent authorities could consequently tap into such repository, enabling them to build on each other's expertise and possibly accelerate processes. An existing platform which could potentially be leveraged for this purpose is the European Network on International Cooperation on Medicines (IntCop) which brings together the EMA, the European Commission and international affairs experts from all EU national competent authorities.

Conclusion

The Alliance invites the Commission, all relevant EU institutions and Member States to take its recommendations into consideration when developing measures to strengthen the resilience of supply chains for Critical Medicines. In particular, the Alliance is looking forward to the Critical Medicines Act, which the Commission should be tabling shortly. In this context, the Alliance tasks its steering board to monitor and report on the implementation of its recommendations.

The Alliance also considers that this report is a first step, which has focused on priority areas for action. There are numerous other areas, which will need to be considered for discussion and possible recommendations for actions. The Alliance is looking forward to working with its members on these, and counts on the continuous support from the Commission to help it in this endeavour.

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Annex

Annex I: Vulnerability Assessment methodology

Details of the Vulnerability Assessment methodology

1. **Adopt a two-stage method to assess medicine vulnerability**, in order to achieve a comprehensive analysis of critical medicine vulnerabilities. An initial phase will allow the shortlisting of the most vulnerable medicines through a series of quantitative indicators. The molecules identified as vulnerable at the end of the first phase will be included in the Vulnerable Medicines List and undergo the second phase aimed at refining the nature of vulnerabilities using a combination of more detailed quantitative and qualitative indicators. At the request of Member states, a challenge procedure will be available. This procedure shall allow the assessment of molecules that are not initially (at the end of the first phase) identified as vulnerable in light of other vulnerability factors. If these molecules are found to be vulnerable based on the new qualitative and refined quantitative indicators, they shall be added to the list. The precise modalities of the challenge procedure will be defined later.

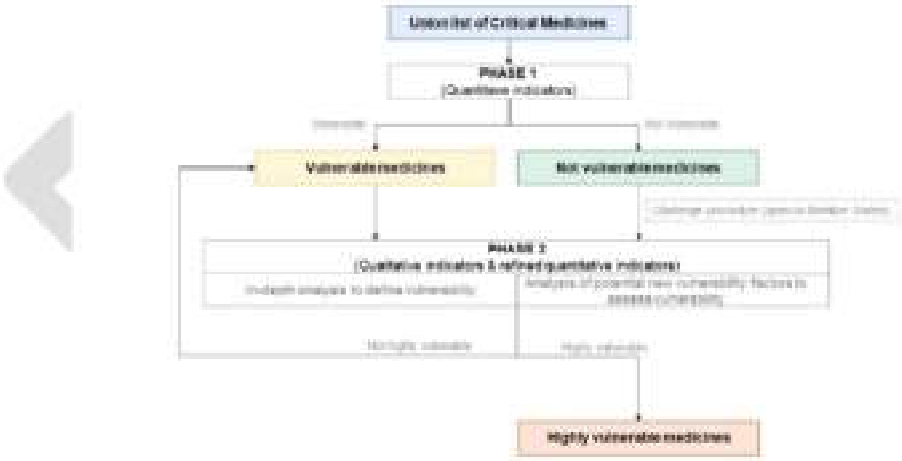

Figure 1: Visual representation of the two stage process

[1] Patent medicines, due to their specific characteristics and the better resilience of their supply, are not intended to be included neither within the vulnerability assessment nor the future list of vulnerable medicines.

2. **Use the vulnerability indicators identified, defined and majority validated by the members of the *Critical Medicines Alliance***. Based on a pilot exercise conducted by DG HERA/GROW and the expertise of various stakeholders of the pharmaceutical ecosystem, the Critical Medicines Alliance has developed a set of indicators of vulnerability, associated with relevant items to operationalise the assessment.

		Type of Indicator	Proposed items
PHASE 1	**Industrial presence**	Quantitative	- Share of active production sites within and outside EU for API, F&F and P&L. Key elements underpinning potential partnerships.
	Diversification	Quantitative	- Number of production sites alongside the supply chain per phase for API, F&F and P&L. - Number of countries with manufacturing sites per phase for API, F&F and P&L.
	Market concentration	Quantitative	- Respective market share / number of MAHs on a given product.
	Supply chain risk	Quantitative	- Number of shortages or risks of shortages declared in the past defined period (duration to be defined later)
	Unpredictable demand	Quantitative	- Sales variability, γ, seasonality and epidemiology
PHASE 2	**Market concentration (refining)**	Quantitative	- Distribution of volumes of API, F&F, P&L between manufacturers.
	Unpredictable demand (refining)	Qualitative	- Identification as a strategic medicine in case of crisis. - Evolution of therapeutic indications. - Risks associated with social phenomena (medication misuse) - MAH market exits and/or newcomers
	Economic viability	Qualitative	- Price volatility of API and raw materials. - Complexity related to product specificity - Environmental, social and safety aspects

			related to specific productions

N.B: *Further details regarding the criteria/items, their objectives, and their implementation can be found in the concept note "Vulnerability Assessment" in Appendix.*

3. **Examine the feasibility of using predictive analysis tools to anticipate shortages.** In the current vulnerability assessment methodology, consideration of past shortages is ensured by the "Supply Chain Risk" indicator. However, the use of predictive analysis models to anticipate future shortages would allow for a more exhaustive analysis. In this regard, the inclusion of predictive analysis in the methodology should be carefully studied as it can yield significant insights into supply chain vulnerabilities and subsequent availability of Critical Medicines.
4. **Creating a macro-indicator to identify medicines for inclusion in the list of Vulnerable Medicines.** The creation of a "*Supply Vulnerability Index*" aggregating the indicators of the first phase will enable a rounded analysis of the vulnerability of the medicines under study. For each item, thresholds will be set to determine whether the medicine presents a vulnerability on the given indicator. Then, at the conclusion of the first phase of the analysis, if the medicine is vulnerable on a defined number of indicators and thus scores higher than a defined threshold, it will be included in the list of Vulnerable Medicines.

5. **Consultation with experts to determine the thresholds and weighting for the macro-indicator.** Given the importance of calibrating the quantitative parameters and to ensure alignment with health and industrial realities, the expertise of specialists (both technical and decisions scientist) should be mobilised to define thresholds beyond which vulnerability is identified for each indicator, as well as the weighting to be assigned to each indicator within the macro-indicator. These experts may come from the authority responsible for establishing the list, as well as from external institutions and academia with expertise in the field.

Considerations on the development of the future list of Vulnerable Medicines

6. **Conduct periodic updates of the list of Vulnerable Medicines.** The CMA stakeholders emphasised the necessity to adopt an iterative approach to construct the list of Vulnerable Medicines. Therefore, periodic updates using the latest available data should be conducted.

Periodic updates will allow for the reassessment of medicines on the vulnerability list, taking into account changes in supply chains and the broader pharmaceutical market, including new medicines added to the EMA's Critical Medicines list.

7. **Implementing the required measures to achieve an actionable list at the earliest time.** The list of Vulnerable Medicines shall serve as a reference to prioritise supply chain reinforcement actions developed by the EU and the Member States. Thus, **the Critical Medicines Alliance considers it imperative to establish a preliminary draft list of Critical Medicines by mid-2025, with a view to full implementation by the end of the same year**. To facilitate the timely achievement of this objective, a number of interim actions should be undertaken:
    - **Conducting the vulnerability assessment in successive batches**. A batch approach would facilitate the acquisition of preliminary results while distributing the burden of data transfer for Member States and market authorisation holders. This approach would also pinpoint weaknesses in the methodology and offer room for optimisation.
    - **Transitionally, use temporary vulnerability assessment results to prioritise initial actions.** Conducting a two-phase vulnerability assessment will ultimately yield a comprehensive evaluation of supply chain vulnerabilities for Critical Medicines. However, to synchronise the respective timelines for compiling the list and initiating the first measures, the employment of partial analyses may be appropriate on a temporary basis. In particular, the shortlist resulting from the first phase of the vulnerability assessment (mid-2025) may be utilised while awaiting the qualitative analysis.
8. **Involving the *Critical Medicines Alliance* in the development of the list of Vulnerable medicines.** The technical phase of developing the list is out with the Alliance's mandate. Nonetheless, the stakeholders of the Critical Medicines Alliance shall be closely associated to technical decisions, particularly Member States representatives due to their implication in data generation and transfer.

Annex II: Considerations for public procurement rules

- **Actions on Public Procurement Specifications: Eligibility requirements**

The requirements outlined in public procurement specifications will, at a minimum, address the following aspects:

1. **Security of Supply Requirements**

- The supplier should ensure the availability of Critical Medicines by maintaining required stock levels or establishing contracts with raw material suppliers to guarantee a reliable supply.

2. **Environmental requirements:**

- Requirements will include compliance to Environmental Management Systems, and risk evaluation in accordance with data provided under the Environmental Risk Assessment (ERA) as mandated by Directive 2001/83/EC.
- **Actions on Public Procurement Attribution : Criteria**

At a minimum, the following bid evaluation criteria will be implemented:

1. **Security of supply criterion**

- Real-time monitoring and traceability of supply chain components to enhance visibility throughout the chain and enable the rapid identification of potential issues (involving patients and representatives).

2. **Resilience Criterion:**

- Number and location of diversified suppliers to reduce dependency on single sources, especially for raw materials or critical components.
- Number of API production sites in the EU (% of sourcing from the EU vs. outside the EU).
- Number of Finished Products production sites in the EU (% of sourcing from the EU vs. outside the EU).

3. **Environmental Criterion:**

- Carbon footprint assessment of production and supply chain processes.
- Environmental management system for the production of active substances and finished products, including risk assessments, environmental routines, environmental audits, and sanctions for non-compliance with environmental agreements/routines. To achieve the highest score, the environmental management system should be certified by a third party.

Additional sub-criteria may be added based on the findings of the study that will be launched by the Alliance regarding regulatory asymmetry (concerning environmental and social standards) between EU and third countries and its impact on competitiveness, public health and environmental risk.

- **Actions on Legal Clauses**

To ensure the reliability of tenders in terms of technical quality and logistics, public procurement contracts could include the following clauses:

- **Security of supply clauses,** including timely delivery obligations and reliable manufacturing processes
- **Environmental responsibility clauses,** including the development of a long-term roadmap outlining future environmental impact projections and actions required to mitigate this impact.
- Additional conditions could include guaranteed **production capacity reserves** to ensure rapid scaling during supply shocks.

Annex III: Methodology for international partnerships

A) Types of partnerships

Four types of international partnerships are proposed to enhance EU pharmaceutical supply, each with their own objectives. For the purposes of these recommendations, "international partnerships" refer to cooperative relationships between the EU and non-EU countries, regions, or organisations to achieve mutually agreed objectives. Participation in partnerships is not mutually exclusive.

The proposed international partnerships are as follows:

Leveraging existing partnerships

Established trade partner countries

Goal of partnership: to strengthen and facilitate existing trade relationships with trade partners who possess significant pharmaceutical production capacity and established regulatory standards. Focusing on strong, proven trade connections, these partnerships prioritise continuity, security, and resilience in the pharmaceutical supply chain.

This partnership type should include the following objectives:

1) Commit to facilitate timely cross-border movement of medicines and inputs

2) Evaluate current trade agreements (strengths, weaknesses) and explore ways to enhance effective implementation of these, for instance by reducing and not imposing trade barriers, including tariffs, where appropriate, while ensuring that the EU patient safety and quality standards will be maintained

3) Support regulatory cooperation, including for manufacturing through exchange of information on manufacturing capabilities and supply chain vulnerabilities, as well as on regulatory best practices to develop harmonised and effective regulatory policies, procedures, and standards, and commit to adequate enforcement and compliance with such standards

4) Promote innovation, including in production processes, through skills development and voluntary technology transfer

5) Promote scalable manufacturing capacity expandable beyond domestic needs in the case of pandemics or seasonal disease peaks

6) Examine possibilities to co-invest in strategic projects

Large producer and spare capacity countries

Goal of partnership: pragmatically explore ways to work with third countries to prevent supply chain disruptions.

The production of inputs for generic medicines has increasingly shifted outside Europe, particularly to China and India[32]. This reliance on a limited number of external suppliers, coupled with limited diversification options for manufacturing Active Pharmaceutical Ingredients (API) in the EU, has raised concerns about supply security. Over-dependence on a few suppliers makes global supply networks vulnerable to disruptions.

At the same time, it is essential to adopt a pragmatic approach in the short term, notably to maintain current partnerships and trade to prevent supply chain disruptions and strengthen their resilience as well as quality of supply.

This partnership should include the following objectives:

1) Commit to ensure ongoing cross-border movement of medicines and inputs

2) Strengthen resilience of partnerships through information exchanges and support for alignment with EU standards, in parallel with the long-term intention to reduce dependencies via enhancing capacities in Europe

3) Evaluate current trade agreements (strengths, weaknesses) and explore ways to enhance effective implementation of these

4) Support regulatory cooperation and optimization, ensuring the adequate enforcement of regulatory policies, procedures, and standards

6) Exchange information on manufacturing capabilities

7) Strengthen commitment to uphold and advance environmental and social standards, while preserving affordability of costs.

Intensifying and building new partnerships

Neighbouring and strategically positioned countries

Goal of partnership: foster future pharmaceutical supply chains that will enhance resilience and diversification by collaborating with neighbouring or strategically positioned countries with moderate but potentially growing pharmaceutical production capacities and significant geopolitical importance to the EU.

In doing so, the EU can broaden its supply base, reduce dependency on any single source or region, and strengthen supply chain security for Critical Medicines. This can be achieved through both short- and long-term actions, depending on the level of pharmaceutical production capacities in third countries. By partnering with accession candidate countries and potential candidates, the EU could strengthen the overall supply chain, ensuring that medicines meet the same high standards of quality and safety as

those produced within the EU. This alignment is achieved through the adoption of the EU *acquis*, which sets rigorous requirements for production, distribution, and regulatory oversight, creating a seamless integration with the EU's quality framework. Action can also build on existing Deep and Comprehensive Free Trade Agreements, such as those with Ukraine and Moldova, where applicable.

Such partnerships reflect the priorities of the New Growth Plan for the Western Balkans, which seeks to promote integration into industrial supply chains, as well as this Commission's priority for enlargement. These partnerships can be built through both political engagement and with members of the Critical Medicines Alliance from this region.

This partnership should include the following objectives:

1) Contribute to the diversification of supply chains, including via EU strategic investments
2) Reduce lead time and vulnerability to climate and/or transport upheaval
3) Identify manufacturing potential in relevant countries

Capacity-development countries

Goal of partnership: identify future opportunities to cultivate and expand pharmaceutical production capacity in low- and middle-income countries (LMICs) in a mutually beneficial manner.

This partnership type builds on the premise that more sustainable and diverse global production will benefit people around the world, including those in the EU. It should support ongoing initiatives building production capacity for local demand in a third country. In the long-term, this partnership should ensure the sustainability of investments by fostering an environment that also enables exports and strengthens trade between the European Union and LMICs.

Action can build on current and previous EU initiatives, including actions under the Global Gateway and Team Europe to build local manufacturing capacity. Given the nature of this partnership, most objectives and associated actions will occur within a long-term timeframe.

This partnership type should include the following objectives:

1) Explore the possibility of greenfield projects and pool financing mechanisms/means that could support these
2) Strengthen commitment to upholding and advancing rights of employees, social, and environmental and social standards
3) Identify manufacturing potential
4) Promote regulatory convergence and increasing the standard of production, including by inviting these countries to join multilateral fora and international organisations that promote the development of standards and regulatory convergence in the field of pharmaceuticals
5) Support innovation of production processes, including through skills development and (voluntary) technology transfer

B) Development of the Methodological Framework

Prioritising countries for different partnerships should consider various evaluation criteria and that the relative importance of the criteria depends on the type of partnership under consideration. It is recommended to prioritise countries using the multi-criteria decision analysis (MCDA) approach. MCDA allows the evaluation of alternative options towards achieving multiple objectives, by eliciting value preferences against a set of criteria while considering their relevant importance. This allows establishing a transparent link between the available data and value judgments, by distinguishing between alternative options' performance and valuation, thus facilitating prioritisation or ranking decisions.

The required methodological framework was developed by specifying the decision context and identifying the value criteria. These were established by eliciting feedback from members via surveys and workshops, presenting the draft framework, and obtaining member feedback to finalise it.

Decision context

- **Aim of the exercise:** To prioritise countries relevant for the four types of partnerships. The partnerships were drafted as part of decision context development. A single country can be prioritised for multiple partnership types (i.e. the categories are not mutually exclusive).
    - The Alliance recognises that the country of manufacturing is not the sole determinant of corporate conduct or cost of manufacturing for a given company in a given country. The market on which a product is going to be placed, including the EU, informs the standards. Global pharmaceutical companies that operate across geographies, both as it relates to manufacturing and distribution and supplying medicines to patients across the world, uphold corporate and globally applicable standards regardless of location of operation.
- **Decision makers:** The Alliance makes recommendations, and the European Commission ultimately makes the decision. The outcomes of the CMA, through the Strategic Report and its recommendations will feed into the preparatory work of the Critical Medicines Act.
- **Alternative options:** Countries to be considered. In practice, these vary by partnership and will be specified when applying the framework.
    - **Any country** considered for an established trade partnership with the EU needs to have regulations that ensure Good Manufacturing Practice (GMP) compliance of produced materials or medicines. If a country does not have such regulations, it will not be considered an "Established trade partnership country", but may be considered under one of the other three remaining categories.
- **Stage of the pharmaceutical supply chain:** Recommendations are not limited to certain stages of the supply chain but are considered as a criterion (production capacity of key outputs of the various stages of the pharmaceutical supply chain).
- **Medicine type:** Focus on all medicines on the Critical Medicines List, appreciating that the list is dynamic, i.e. subject to change.
- **Decision time frame:** The current country prioritisation is a one-off exercise.

Value criteria

A total of 18 key criteria were identified and classified into four categories: production capacity (four criteria), ease of trade (six criteria), third-country policy (four criteria), and geographical/geopolitical factors (four criteria).

Production capacity/presence

Different stages in the value chain have varying dynamics in terms of production. Understanding the ability of economic operators in a third country to be a source of production and exports of relevant pharmaceutical components, including regulatory starting material, GMP intermediates, active pharmaceutical ingredients, or finished dosage forms will support the CMA's goals on identifying the potential of countries for international partnerships.

When production capacity data are not readily available and neither can be obtained, industrial presence may be used as an indicator to understand the overall baseline ability of economic operators in a third country to act as sources of product supply.

1. **(Regulatory) starting material production capacity/presence:** First GMP-compliant chemical and biological substances.
2. **GMP intermediate production capacity/presence:** GMP-compliant intermediate substances between regulatory starting material and active pharmaceutical or biological ingredient.
3. **Active pharmaceutical/biological ingredient production capacity/presence:** Key ingredients that provide the desired effects of the medicine that are GMP-compliant.
4. **Finished dosage form production capacity/presence:** The GMP-compliant final drug product obtained by blending APIs and excipients.

Ease of trade

The pharmaceutical and larger trade relationship between the EU and third countries will influence the ease of trade of Critical Medicines between the two. Factors contributing to the relative ease of trade include existing agreements, trade relationships, and other trade policies.

5. **Trade flows**: Existing trade data on imports into the EU of finished medicines provide an indication of source countries' integration into international value chains and openness to trade. Export data will also help understand how much a potential partner third country also sources medicines from companies in the EU.
6. **Regulatory standards**: If a third country has regulatory standards for pharmaceuticals similar to those of the EU, this could facilitate the process of trade between the EU and third country in Critical Medicines. Additionally, if a third country does not have regulatory standards similar or equivalent to EU standards, it needs to be identified whether companies operating in those countries meet the EU requirements.
7. **Pharmaceutical agreements:** Countries with GMP Mutual Recognition Agreements (MRAs) recognise each other's manufacturing standards, and the EU may waive batch testing or certain biological starting material establishments (e.g. plasma collection centres), speeding up manufacturing and time to access of patients to imported medicines. EU candidate countries and

potential candidates are obliged to gradually align with all EU *acquis* in this area (as well as all other *acquis* areas).

8. **Free trade agreements or other partnership agreements:** Free trade or other partnership agreements/engagements (e.g., association agreements or Trade and Technology Council (TTC)) with the EU may cover pharmaceuticals, APIs, etc. Such agreements may also bring other advantages, such as tariff liberalisation, clear procurement rules, and a forum for regulatory dialogue.
9. **Regulatory collaboration, including previous collaborations during shortages**: Broad regulatory collaboration, including previous collaborations with between the EU and third country regulators during specific medicine shortages, may provide operational evidence of insight into the feasibility of collaborations for future shortages.
10. **Protectionist trade policies**: The existence of protectionist trade policies and other trade barriers for medicines in third countries (e.g. export restrictions, subsidies, discriminatory public procurement, etc.) may limit EU imports into these markets thus hindering market access of EU-based manufacturers and exporters. Such policies also diminish the level playing field for EU products since the EU remains one of the most open markets in the world.

Third country policy

Third country policy regarding pharmaceutical production is relevant in examining potential partnerships. This includes understanding how safety, quality and other standards align with those recognised by the EU or internationally.

11. **GMP compliance**: Alignment with EU / International quality standards (EUDRALEX and International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)) to ensure that products are consistently produced and controlled. It is crucial for safeguarding public health by ensuring the safety, efficacy, and quality of medicines.
12. **Diversification or supply resilience policy**: If a third country has a policy measure for medicines supply chain resilience or diversification, it could provide an existing 'landing zone' for a bilateral agreement with the EU. Examples include the Medical Supply Chain Resiliency Act (draft US legislation) and national resilience strategies (e.g. Japan, Canada, and the UK).
13. **Environmental standards:** Alignment with EU or, where appropriate, globally recognised environmental protection standards as they relate to the manufacturing of pharmaceuticals. Consideration of further potential protections, including compliance with relevant national legislation of the respective third country as well as international conventions, regulations, and instruments on environmental rights and conduct, including sector specific standards.

Moreover, good and standard practices include global environmental health and safety (EHS) programs, principles, and technical requirements that establish global minimum operating characteristics for a variety of environmental, health, and safety aspects[33].

14. **Worker protection:** Alignment with EU (e.g. EU Directive on Safety and Health at Work) or globally recognised worker protection and standards (e.g. International Labour Standards) as they relate to the manufacturing of pharmaceuticals. Legislation covering health and safety, working conditions, and compensation, for example, can contribute to providing adequate worker protection for pharmaceutical manufacturing.

Geographical/geopolitical factors

Geographical and geopolitical factors will influence the context in which a partnership is developed. This includes both the relationship between the EU and the third country and political and social conditions within the third country itself.

15. **Geographic proximity:** Proximity to the EU may reduce lead time and vulnerability to transport upheaval[34].
16. **EU membership status:** The potential for the third country to enter the EU in the future. Eventual membership and the process leading to it, leads to full entry into the EU single market and includes the obligation of full alignment with EU regulatory standards (EU *acquis*).
17. **Political stability:** Countries with stable political environments are less likely to experience disruptions that can affect supply chains.
18. **Corruption:** Level of expected corruption in the third country.

Application of the Methodological Framework

The Alliance recommends that the Commission will apply the methodological framework in 2025 to identify countries most suited for each type of partnership. It should also identify how these partnerships can be operationalised, including with which policy tools.

The recommended application of the methodological framework requires the following steps in the course of 2025:

- selecting which countries to evaluate as alternative options for each partnership (decision context definition),
- establishing qualitative or quantitative measurement scales for the selected criteria (criteria definition),
- gathering evidence on country performance on the criteria relevant for partnerships they are considered for (data collection and options scoring),
- establishing criteria weights (criteria weighting),
- aggregating data to establish overall estimates of value (scores and weights aggregation),
- and lastly developing decision recommendations based on the value estimates (recommendations).

Following applying the methodological framework and identifying countries suitable for partnerships, the Alliance recommends focusing on the design and specific actions of these partnerships to ensure they deliver mutual benefits. This process should carefully account for the unique characteristics and context of each country, while aligning with the overarching of the partnership. Key steps include selecting appropriate policy tools and instruments, along with establishing mechanisms to ensure their effective implementation.

Criteria weighting

Draft measurement scales have been proposed for the 18 criteria, but these may need to be revised based on data availability identified during the framework's application. It is recommended to elicit criteria weights from Alliance members using a workshop-based swing weighting exercise. The weights will be elicited separately for each of the four partnership types; that is, the relative importance of the criteria may differ based on the partnership. The criteria weights will assume that aggregation is done with an additive multi-attribute value model. The workshop may also elicit criteria scale scoring if categorical scales are used. Agreed-upon criteria weights will then be used to establish overall value estimates for each country in each relevant partnership.