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Critical Medicines Act

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

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A Medicines for Europe proposal

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In recent years, the calls for open strategic autonomy in healthcare have been supported by many stakeholders across the EU, including Member States, the European Commission, civil society, industry and academia. To ensure equitable access to high-quality, safe, effective and affordable off-patent medicines and active pharmaceutical ingredients (APIs), a **Critical Medicines Act (the Act) should be adopted**, in line with the goals of the Critical Medicines Alliance and as announced by President von der Leyen's statement to the European Parliament in July 2024.

The Act should aim to address the structural challenges of the EU in relation to the open strategic autonomy of medicine and active pharmaceutical ingredients (APIs) production and medicine shortages by adopting a multi-dimensional approach focusing on the following critical pillars:

Pillar 1

Designing an investment framework for resilient manufacturing of critical medicines and APIs in Europe

Pillar 2

Addressing the root causes of industrial consolidation and medicine shortages: towards more sustainable market policies

Pillar 3

Ensuring solidarity-based stock allocation and downstream supply chain visibility

Pillar 4

Building international partnerships and promoting open trade

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Addressing the skills shortages

Pillar 1

Designing an investment framework for resilient manufacturing of critical medicines and APIs in Europe

Pillar 1- Designing an investment framework for resilient manufacturing of critical medicines and APIs in Europe

The recent vulnerability analysis[1] conducted by the European Commission Directorate for Health Emergency Preparedness and Response (DG HERA) of selected critical medicines, as well as numerous other studies[2] performed by and for the European Commission in recent years, highlighted that the European medicines supply chain is heavily consolidated which threatens the security of medicines supply[3].

The new European Commission should prioritise the security of medicines supply by allocating dedicated EU funds for investment in the manufacturing of critical medicines and active pharmaceutical ingredients (APIs) in the new Multi-Annual Financial Framework. In addition, the condition for participation in the existing and prospective State Aid, regional aid and Important Projects of Common European Interest (IPCEI), should be adapted to allow the participation of off-patent medicine and APIs manufacturers. Under the current rules, only research, development and innovation projects using novel technologies can be financed which limits the possibility to invest in the manufacture of most medicines on the Critical Medicines List. Regional aid rules restrict the possibility of investing in existing industrial parks which have the infrastructure to support medicine or API manufacturing. To remedy this, as also stressed in the recent Draghi report on the future of the EU Competitiveness[4], **the definition of innovation in the IPCEI should be expanded to include manufacturing processes for the green and digital transitions and for the security of supply with regional aid limits being more flexible**. In addition, the process for receiving funding should be clear and straightforward, with more simplified procedures for the selection and allocation of funds than those currently in place. This will enable EU manufacturers to invest in novel processes and technologies for supply security and adherence to strict EU environmental and chemical regulations. An updated definition of "first-of-a-kind" facilities which contribute to the security of supply of medicines and APIs can be as follows:

[1] Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report: https://health.ec.europa.eu/publications/assessment-supply-chain-vulnerabilities-first-tranche-union-list-critical-medicines-technical-report_en

[2] European Commission Staff Working Document, "Vulnerabilities of the global supply chains of medicines, Structured Dialogue on the security of medicines supply" (2022); European Commission Staff Working Document on strategic dependencies and capacities (May 2021); The Technopolis study ''Future-proofing pharmaceutical legislation Study on medicine shortages: final report'' (December 2021); etc.

[3] Studies performed by Teva Europe: The case of Europe's disappearing medicines cabinet, 2023; Teva Critical Medicines Health check, 2024

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

'First-of-a-kind facility' means a new or substantially upgraded active pharmaceutical ingredient or finished dosage form (medicine) manufacturing facility, or a facility for the production of other critical components (key starting materials, key intermediates) predominantly used in medicine or active pharmaceutical ingredient manufacturing, which provides innovation with regard to the manufacturing process or final product that is not yet substantively present or committed to be built within the Union, including innovation that concerns improvements in automation, continuous manufacturing, yield improvements or other chemistry or biotechnology processes that contribute to an increase in the level of security, safety or reliability, energy and environmental performance of the production process or site, that would enable the reintroduction into Europe of production that would be compliant with EU chemical, biotechnological or environmental regulations (whereas it may not be compliant in productions outside of Europe), or in the implementation of production processes or other investments on the site that reduce energy, solvents, waste or water resource use in resource intensive chemical or biotechnological processes.

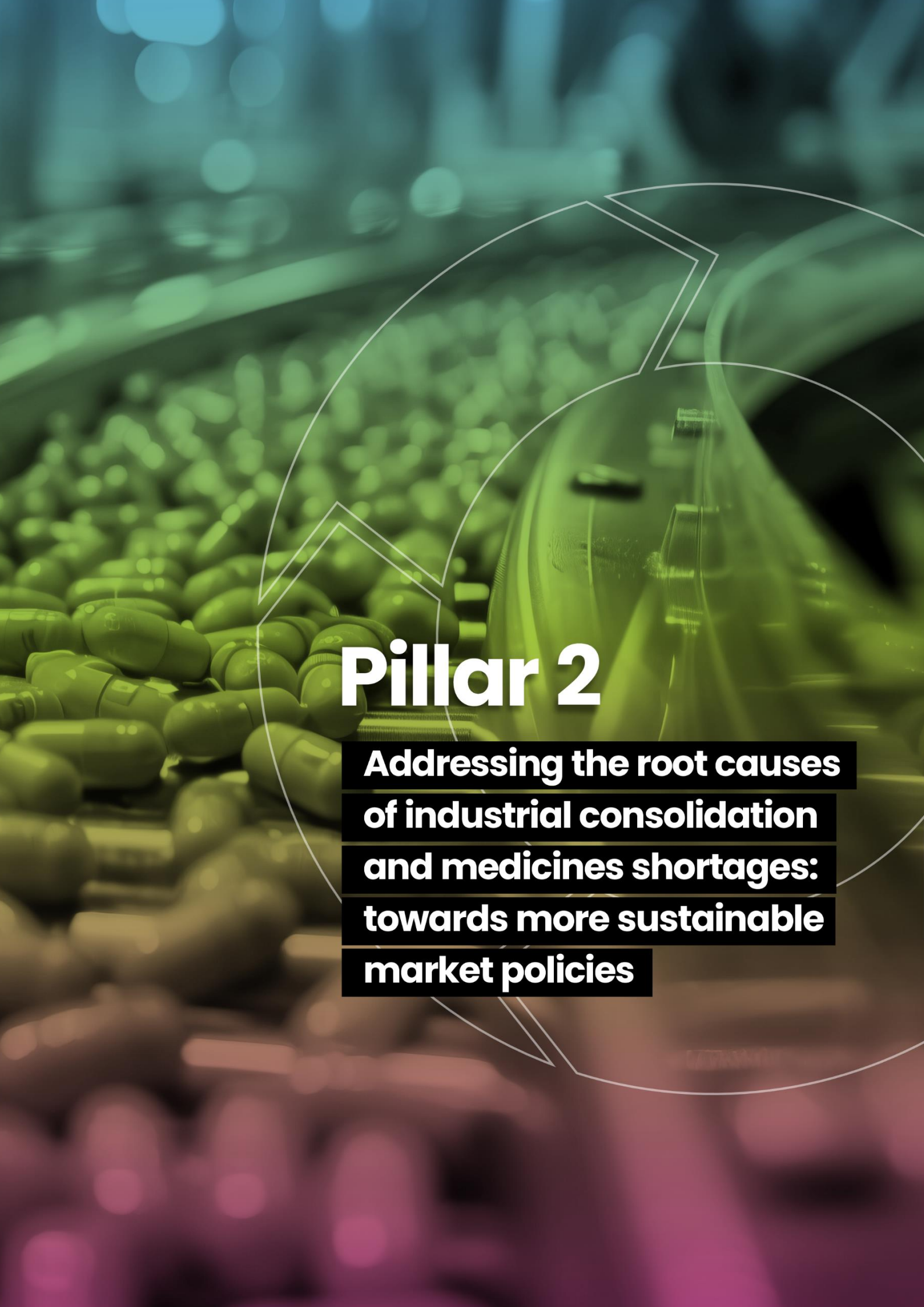
Other criteria for funding under the Critical Medicines Act as well as further explanations are outlined in the table below.

What could be funded/exempted from state aid	**Justification**	**Market failure explanation**
New or upgraded API, FDF, KSM or critical intermediate production in Europe.	Geopolitical de-risking Diversified production and reduced dependency on one production geography, mitigating the risks associated with disruptions in the global supply of medicines, such as trade barriers, geopolitical tensions, or unexpected events like pandemics or natural disasters.	There is clear evidence that, in relative terms, medicine and off-patent API manufacturing has shifted to Asia with the highest growth in China. If ramping up production of APIs in Europe is a real target, for some KSM we would need to offset the cost of compliance with EU environmental/chemical/green deal regulations.
Investments in **innovative production** processes:		Overall, there is no reward in off-patent markets for the security of supply, safety, or environmental improvements.
- Automation	Automation streamlines production processes,	

	improving efficiency and productivity, and offers greater agility and flexibility in responding to market demand fluctuations. Companies can quickly adjust production levels, ramp up or down, based on changing customer needs or market conditions.	
- Reduction in the use of dangerous materials (such as flammable solvents, etc….)	Investments in reducing the use of dangerous materials reduce the risk of accidents or incidents that could disrupt the supply chain. By adopting safer alternatives or implementing robust safety measures, companies can prevent potential disruptions caused by material shortages, regulatory compliance issues, or environmental concerns.	
- Continuous manufacturing	Continuous manufacturing enables standardised and repeatable production processes, ensuring consistent product quality, as well as seamless integration of production stages	
- Full processes that decrease the use of energy/solvents, substitution of solvents by water,	Processes that reduce the use of energy and solvents, as well as potentially substitute solvents with water, minimise energy consumption. The reduced reliance on solvents and the use of water as a substitute can mitigate the risk of supply shortages or price fluctuations associated with specific solvents.	

- Low-temperature chemistry processes (energy saving, hazard reducing),	Adoption of low-temperature chemistry processes can reduce energy consumption thereby reducing the environmental impact and minimising the dependence on energy resources.	
- Switch to enzymatic chemistry,	Enzymes are highly selective and operate under milder conditions, requiring lower temperatures and less energy. By transitioning to enzymatic chemistry, companies can improve process efficiency, reduce the environmental footprint, and optimise resource utilisation.	
- Yield improvement technology (biotech)	Optimising the yield of production processes enables companies to maximise the output of desired products from available resources, reducing waste, improving cost-effectiveness and increasing overall process efficiency	No reward but offset long term by energy savings costs and potentially increased yields
- Improve worker's safety/reduce exposure to harmful chemicals	Employee safety needs to be central in re-shoring any form of manufacturing, with special incentives for processes that improve or maintain the current standards while improving the manufacturing outcomes.	No reward in biosimilar markets but long-term efficiency gains for the manufacturer
Investments that enable production in Europe of chemistry processes that are currently done outside of Europe do not comply	Diversifying/reshoring some production from China/Korea will lead to major costs due to the need to comply with	EU markets will not reward this investment.

with EU regulations like REACH, etc. to produce the final API or some key starting materials (KSM)	regulations such as EU REACH or other regulations. Most of the first-generation antibiotic precursors (e.g.7-ADCA for cephalosporines and 6-APA for penicillins) come from China/Korea. There is some production in Europe through enzymatic reaction (less waste). Same for some statins (cholesterol lowering agents).	
Investments in water or energy efficiency measures like solar panels, water capture, etc.	Water and energy efficiency measures reduce the energy consumption and water use, and overall, the environmental impact of operations. They also reduce the reliance on external resources and build resilience against climate change impacts and water scarcity challenges.	No reward in off-patent markets but some long-term savings for the manufacturers.
Investments in API and FDF production can reduce the risk of batch quality problems (a big source of stock-outs), and FDF production flexibility that can enable rapid reaction to (crisis) demand surges.	On quality: Implementation of Industry 4.0 technologies (i.e. in-process controls), which make quality more predictable.	Requires significant investment and long-term savings through productivity gains and energy savings.



Pillar 2

Addressing the root causes of industrial consolidation and medicines shortages: towards more sustainable market policies

Pillar 2 - Addressing the root causes of industrial consolidation and medicines shortages: towards more sustainable market policies

Whilst investing in the manufacturing of critical molecules in the EU is an important step in restoring the resilience of European pharmaceutical supply chains, achieving long-term resilience is only possible by creating market conditions that support **healthy competition**, enabling multiple players to compete and invest in sustainable supply chains. European pharmaceutical markets need to recognise and reward resilient supply chains.

As stressed by independent European Commission studies[5,6], for off-patent products - which comprise over 90% of products on the EU critical medicines list - the structural root causes of medicines shortages are economic, and related to the functioning of national market policies. In the early 1990s, EU Member States implemented national pricing frameworks designed to encourage the uptake of generic medicines and steadily lower prices. Many critical medicines, which have been on the market for decades, are now subject to aggressive pricing policies. When combined with unsustainable procurement practices, and additional budgetary measures such as clawbacks, paybacks, and other cost-containment strategies, these policies have put significant pressure on manufacturing. As a result, manufacturers have been forced to streamline and consolidate their supply chains and processes to meet these pricing demands, which has inadvertently increased the risk to supply security by concentrating production and reducing flexibility.

1. New pricing models for critical medicines: implement competition-sensitive pricing policies

A sustainable generic medicines marketplace balances the supply and uptake of medicines to ensure continued access. A medicine pricing policy with the sole purpose of reducing pharmaceutical expenditure (e.g. reference prices or mandatory price reductions) does not allow for price adjustments to reflect changes in the cost of goods and production, and negatively affects the reliability of the supply of medicinal products. All economic operators involved in the supply chain are directly or indirectly affected by the applicable pricing mechanisms. The profitability of these entities is critical to business continuity and supply. There is strong price competition in the pharmaceutical market, also known as the "race to the bottom" of prices. This practice does not incentivise MAHs to invest in the production of older generics that have little potential for returns. A consequence of this trend is the withdrawal of medicines – over 50% of the generic oncology

[5] European Commission: Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M., Davé, A. et al., Future-proofing pharmaceutical legislation – Study on medicine shortages – Final report (revised), Publications Office of the European Union, 2021, https://data.europa.eu/doi/10.2875/211485

[6] European Commission: Directorate-General for Health and Food Safety, *Study in support of the evaluation and impact assessment of the EU general pharmaceuticals legislation – Impact assessment report*, Publications Office of the European Union, 2023, **https://data.europa.eu/doi/10.2875/00611**

medicines on the Union List of Critical Medicines observed a decline in the number of products available[7].

Policymakers should start consistently monitoring the level of competition, notice any changes in a negative direction and take action when deterioration of competition is considered a threat to continued supply, instead of waiting inactively until medicines are no longer supplied. A solution to mitigate the risks of global supply chain disruptions by creating a sustainable environment for European manufacturing. A sustainable European market must reflect the reality of production, R&D and regulatory costs in Europe in pricing and tendering by rewarding companies that invest in the security of our supply chains. To address the current challenges that we are experiencing in Europe, a robust dialogue between regulators and supply chain partners must be established to find the solutions that will best deliver a sustainable supply of medicines to patients.
Given the diversity of pricing policies in EU member states, it may be challenging to adapt common criteria. However, it would be possible for member states to agree with off-patent medicine manufacturers on coherent security of supply criteria, which would be recognised and evaluated in addition to the offered price. This could be done in the context of framework agreements which already exist in many member states for cost containment. Each member state could agree to a series of measures that fit local needs and report them to the EU as part of the general effort to improve the secure supply of medicines.

In this context, **the EU Transparency Directive could provide a framework to ensure that the decision-making processes around pricing are open and consistent across member states.**

2. Harmonising legislation and pricing for secure and affordable critical medicines

Additionally, the Critical Medicines Act should include a mechanism to assess whether other legislations or regulatory measures impact the cost structure of manufacturing and marketing critical medicines. For instance, environmental regulations such as the Urban Waste Water Treatment Directive (UWWTD), nitrosamine or PFAS requirements, and stockpiling mandates may introduce additional compliance costs that can affect production viability. While these regulations are essential for public health and environmental protection, it is crucial that their impact on the pharmaceutical sector, particularly on the pricing of critical medicines, is fully understood and managed.

By **establishing a formal mechanism to evaluate how such measures influence the availability of medicines**, the Critical Medicines Act can ensure that these regulations do not inadvertently drive-up production costs to unsustainable levels, thereby exacerbating supply shortages or pushing

[7] https://www.tevapharm.com/teva-in-europe/reports-and-analyses?utm_source=social+media&utm_medium=LinkedIn&utm_campaign=Teva%27s+latest+reports+and+analyses

prices down further. This would enable a balanced approach that integrates regulatory compliance with the need to maintain resilient, cost-effective supply chains for essential medicines. Such assessments should inform future policy adjustments to protect both public health and the sustainability of pharmaceutical supply in the EU.

3. Introducing strategic medicines procurement

In medicine procurement, incorporating security of supply as an objective in the tender design and the inclusion of pro-competitive Most Economically Advantageous Tender (MEAT)[8] criteria can incentivise manufacturers to make strategic investments in more robust supply chains. For a more successful demand-side policy over the longer term, there must be an alignment across the EU, especially for criteria that impact the supply chains and manufacturing processes of companies operating globally.
In addition to supply resilience, procurement can also significantly incentivise and reward environmentally sustainable practices in line with the EU Green Deal and its policy objective through the introduction of environmental criteria. These criteria can include adherence to applicable industry standards and other self-regulated best practices for responsible wastewater management, greenhouse gas (GHG) emission reductions, and the promotion of sustainable practices throughout the pharmaceutical supply chain.

Together with the *European Commission's legal guidance on medicines procurement* and the revision of the EU Procurement Directive, a Critical Medicines Act should provide direction on how to establish clear rules for public procurement of off-patent medicines, setting recommendations on appropriate design on tenders and propose criteria beyond price (MEAT criteria), based on the EU priorities, such as environmental sustainability and supply chain resilience. By adopting these measures, the procurement process can safeguard the availability of critical medicines while fostering fair competition and compliance with EU environmental regulations.
More detailed proposals on reforming the national procurement policies for off-patent medicines are available in the Medicines for Europe position paper: "Medicines Procurement Reform: Strengthening Supply Security through EU guidance".

[8] Directive 2014/24/EU on public procurement introduced the concept of most economically advantageous tender (MEAT) criteria, which take into consideration aspects other than the lowest price, such as security of supply, environmental investments and long-term sustainability.

Pillar 3

Ensuring solidarity-based stock allocation and downstream supply chain visibility

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

Matching supply and demand are essential to ensure timely delivery of medicines to patients in need. Countries across the EU take various measures to ensure an adequate supply of products in the national markets, often to the detriment of the overall goal of shortage prevention across the EU.
The current trend of excessive and uncoordinated national obligations for MAHs to hold additional safety stocks poses significant risks to the pharmaceutical supply chain, patient access to medicines, and market dynamics. For generic medicines, where production volumes require manufacturing at the limit of its capacity, building any additional stock is challenging and can impact the availability of medicinal products within Europe through the higher risk of pruning/portfolio reduction, from Europe to other geographies and vice versa. It is, therefore, crucial to focus on:

- strengthening and expanding the existing supply chain capacities (as outlined under Pillar 1), and;
- optimising the allocation of existing stock by adopting **a new supply and demand monitoring strategy** building on various tools and available data to ensure manufacturers' ability to supply patients at all times.

The **new supply and demand monitoring strategy** should incorporate several critical elements including:

1. Replacing national, and unharmonised safety stock obligations and stockpiling requirements with:
    - Solidarity-based approaches for better stock-sharing through the **European Solidarity Mechanism**:
        - Most medicines shortages occurring in the EU are usually concentrated in a single country and can be resolved quickly by moving stock from one market to another.
        - To support the implementation of stock re-allocation, permanent regulatory flexibilities should be introduced (see point 2 below).
    - A **European Strategic Reserve** which is:
        - Targeted: The scope of this emergency buffer reserve should be limited to two specific cases:
            - Preparedness for a public health emergency or other large-scale crisis;
            - For products on the Union List of Critical Medicines with major therapeutic interest and very limited therapeutic alternatives where stockpiling is identified as a prevention or mitigation option by the Risk Assessment.

- Above country obligations: The European Reserve shall replace the uncoordinated obligation on the country levels. MAHs that satisfy the requirements of the Reserve should no longer be obliged to fulfil national obligations. If not ensured, the Reserve will only serve as another hurdle for manufacturers rather than a solution to the existing problem.
- Proportionate and cost-efficient: The scope and size should be defined per product to avoid write-off waste and prevent disruptions to the functioning of the Internal Market. Additional inventories should be economically viable for manufacturers based on reserve access agreements with the purchasing agency (DG HERA). This would provide manufacturers with a proportionate return and allow for the proper holding and management of an emergency reserve.
- Transparent: An EU reserve should be transparently managed with an overview of available stocks and clear (re-) allocation rules and responsibilities. This transparency can be achieved by using the European Medicines Verification System (EMVS).

2. **Reducing regulatory complexity** to support the agility of the supply chain
    - Introduce permanent packaging flexibility measures to facilitate the flow of products across EU markets:
        - EU-wide hospital product pilot for electronic product information;
        - Replacement of paper package leaflets with electronic product information (ePI) as this would dramatically reduce complexity, stock-outs and misallocation across countries;
        - Acceptance of common EU packaging or multi-market packs.
    - In a crisis and/or where there is a major shortage risk, the movement of medicines within and to the EU should be further facilitated to ensure availability in the member states where they are needed the most. Pragmatic solutions should apply not only in a crisis but also in the case of any risk of supply challenges and could include more frequent use of mutual recognition procedures, additional flexibilities on medicinal product labelling, a notification process instead of traditional variation, and single global development for generic medicines

Similarly, improving the management of API variations and increasing flexibility to reduce change management lag time for the supply chain is critical to prevent and address shortages efficiently.

3. **Improve demand predictability and downstream supply chain visibility** by sharing more aggregate data and analysis with the off-patent industry about demand surge risks:
    - Ensuring the alignment and interoperability of data collection initiatives by the ECDC (European Centre for Disease Control), EMA, HMA (Heads of Medicines Agencies) and

DG HERA, together with other data sources such as the European Medicines Verification System (EMVS).

- Sharing more information about epidemiological risks in the EU with manufacturers, such as expected timing of the infectious/flu season and other infectious risks since many of them are increasing globally, or significant changes to prescribing guidelines that increase volume demand.

4. **Use data generated in existing IT systems**, such as the European Medicines Verification System (EMVS) **to predict and prevent medicine shortages**:
   - Coordinating regular monitoring of the demand and supply of medicines to identify factors that may disrupt, compromise or negatively affect the supply of medicines and forecasted demand based on existing data, the work of agencies, and making sure to minimise the burden for undertakings while ensuring that the acquired information can be compiled and leveraged in a meaningful way.
     EMVS can be used to predict and provide early warning of potential shortages as showcased by a pilot project[9] carried out by the industry on 11 antibiotic medicines in June 2024. The results of the project clearly demonstrate:
     - The EMVS data can be successfully used to monitor and predict shortages.
     - The data provides accurate aggregated volume insights at a molecule level.
     - Using the EMVS data within a platform such as the European Shortages Monitoring Platform (ESMP) will significantly speed up analysis and remove the need for MAHs to duplicate data entry.
     - The ESMP will produce more accurate and dynamic results if it obtains data from the EMVS.
     - If the authorities had access to the supply and demand data, anomalies could be identified more quickly, allowing dialogue with stakeholders.

     The industry believes that there is huge potential in this dataset to make better decisions much faster.

[9] The pilot project was conducted by Medicines for Europe and EFPIA. The report of the project was presented during the 6th Medicines for Europe/EFPIA EMVS Workshop on 18 June 2024.

Pillar 4

Building international partnerships and promoting open trade

Pillar 4: Building international partnerships and promoting open trade

The EU trade policy can contribute to a strengthened open strategic autonomy in healthcare by:

- **Ensuring robust, resilient and open global supply chains to safeguard patient access to medicines in Europe and beyond.**

No single country produces all the medicines it requires, and no medicine is manufactured in every country.
Effective risk diversification requires strengthening open trade policies and avoiding trade barriers such as export restrictions. These steps are essential for maintaining the flow of critical goods and fostering a competitive industry. It is important to continue global dialogue on strategies to enhance solidarity and avoid protectionist responses to crises which hinder the flow of medicines and APIs and disrupt supply chains. It is also important to look at indirect trade barriers. While many countries have zero tariffs on the trade of pharmaceutical products, this is not the case for the goods and raw materials used in the manufacturing of pharmaceutical products. Addressing this is a critical part to ensuring sustained access to medicines in Europe and beyond.

- **Establishing partnerships with partner countries as well as accession candidates.**

The European Commission needs to explore opportunities for collaboration with non-EU countries to support efforts in the diversification of supply chains and strengthening international partners. Accession candidates such as Ukraine and Moldova can offer investment opportunities which would both benefit European manufacturers as well as support capacity building at the country level.

- **Continuing collaboration with international partners on the security of supply and solidarity-based responses to crises**

Collaboration with international partners is crucial for strengthening the resilience of the supply chain for APIs and off-patent medicines, improving access to generic and biosimilar medicines, and creating new opportunities for EU-based companies.
The potential of existing bilateral forums, such as the EU-US TTC which also includes a working group on secure supply chains, should be leveraged more and similar or new forms of multilateral cooperation should be established with other strategic partners including key large -scale manufacturing countries.

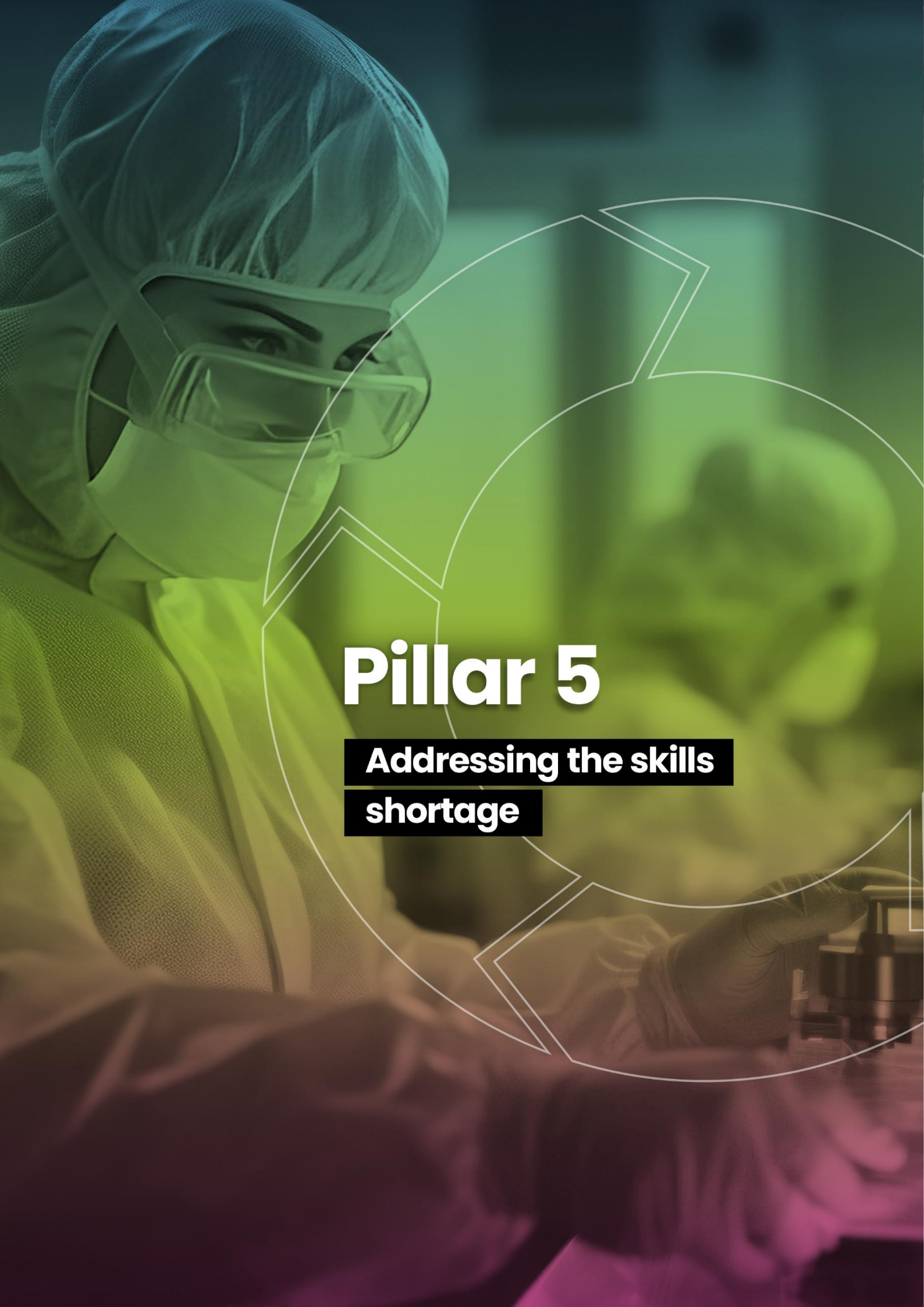
- **Enhanced bilateral and multilateral regulatory cooperation and mutual recognition to increase supply chain efficiency**

Increasing regulatory harmonisation and reliance would facilitate trade and market access and reduce duplications that hamper the capacity to respond to patient needs.

The EU should continue to pursue mutual recognition agreements with key partners to optimise resources, increase reliance and reduce burdens on regulatory authorities and the industry while maintaining high health, quality, environmental and safety requirements.
Cooperation on the single development of generic and biosimilar medicines is also critical to avoid study duplications, reduce development programme inefficiencies and better respond to patient needs.
Mutual Recognition Agreements (MRAs) for pharmaceutical Good Manufacturing Practice (GMP) and their full implementation are essential tools that can support resource savings for regulators and reduce timelines for supplying imported medicines to patients. Import testing requirements currently impose a 30-day average delay in delivering medicines to patients and reduce shelf life.

- **A balanced approach to intellectual property, competition and access to medicines in trade negotiations**

Any negotiation on intellectual property with non-EU countries should be balanced, taking into consideration the effective impact of intellectual property on generic and biosimilar medicines access and healthcare sustainability both in the EU and in the relevant non-EU countries.
Overemphasis on extending the EU's IP standards to non-EU countries could also complicate discussions on regulatory harmonisation, removal of tariffs and non-tariff barriers and cooperation on the security of supply.



Pillar 5

Addressing the skills shortage

Pillar 5: Addressing the skills shortage

The European Union should address the skills shortage by creating, mobilising and retaining new talent in research, design and production, and supporting the emergence of a suitably skilled workforce in STEM - Science, Technology, Engineering, and Mathematics fields. Additionally, reskilling and upskilling of workers are crucial in an industry that requires unique expertise in areas such as biotechnology, biomanufacturing, sustainability, regulatory compliance, quality assurance and logistics. These skills shortages exacerbate existing challenges, including stringent quality standards and the ability to manage major healthcare crises such as COVID-19. Moreover, retaining talent in Europe is essential to maintain and promote competitiveness and R&D in the (bio)pharmaceutical industry. The European Skills Partnership, along with other collaborations, assessments, research and sharing of best practices on education and industry-focused upskilling programmes in vocational schools, training providers and universities, should be strongly supported by the EU:

- Competence centers to promote the use of sector-specific technologies , providing expertise and skills to the stakeholders, growing a highly skilled workforce in Europe
- Specific training actions, particularly upskilling and reskilling of low-skilled workers for employment in an industry that is becoming increasingly technical and digitalised.
- Scholarships for graduate studies.
- Commitments to industrial training under the Pact for Skills.

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