EUROPEAN POLICY CENTRE

POLICY BRIEF

HEALTH AND SOCIETAL RESILIENCE PROGRAMME

1 JUNE 2026

Towards openness-based European preference in the pharmaceutical sector

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EXECUTIVE SUMMARY

The pharmaceutical sector faces mounting pressures from supply chain concentration, geopolitical rivalry and competing industrial policy models. Around 55% of global API production is concentrated in China and India. As China combines strategic planning, public funding and a large domestic market to accelerate biomedicine as a national priority, the US is deploying tariffs, tax credits and fast-tracked approvals to attract investment back home. Europe risks repeating the trajectory of steel, solar panels and electric vehicles: starting from strength and being systematically outcompeted.

The Critical Medicines Act and Industrial Accelerator Act mark a shift towards European preference, in light of the evolving geopolitics and geo-economics. A narrow "made in EU" framing, however, risks fragmentation, higher health system costs and WTO exposure. A more durable model prioritises EU-anchored innovation, diversified supply chains and trusted international partnerships over strict localisation rules.

Manufacturing follows innovation; without improvements to regulatory efficiency, capital availability and pricing frameworks, localisation requirements will be difficult to sustain. Ensuring long-term resilience and the EU's competitiveness also requires protecting the economic viability of critical medicines.

In pursuing strategic partnerships, the EU can build on existing trade agreements and established cooperation with partners such as Australia and Switzerland. It remains unclear how EU-preference rules will be compliant to WTO commitments, and third trusted countries as well as industry are seeking greater clarity.

A further risk lies in legislative incoherence. The CMA, IAA, Biotech Act and the forthcoming Public Procurement Directive revision each contain procurement-related provisions, drafted on distinct timelines. Without active coordination, their interaction could deepen single market fragmentation rather than address it.

Four priorities follow: coordinate legislative instruments before layering them, operationalise evidence-based supply-chain vulnerability assessments under the CMA, default to multi-winner tenders for critical medicines procurement, and align (national) pricing and reimbursement frameworks with EU industrial policy ambitions.

INTRODUCTION

In the face of geopolitical tensions, supply chain disruptions and natural shocks, economic security has become a dominant policy paradigm, profoundly affecting all strategic sectors of the economy. The pharmaceutical sector is no exception. The challenge can be described in terms of a trilemma of dependencies, where optimising for security and availability of medicines, access and affordability as well as competitiveness is an essential, although increasingly difficult task.

In Europe, recent months have seen a clear tendency towards recalibrating for greater EU-based value-creation. This is partly a response to the perceived weakening of Europe's competitive position in the pharmaceutical sector, and the broader emergence of protective approaches around the world, particularly among Europe's key global rivals. Although the pharmaceutical industry is a power engine of the European economy, supporting around 2.3 million jobs and generating over €366 billion annually in exports,[1] concerns are mounting about its long-term competitiveness and resilience.

The COVID-19 pandemic exposed the risks of highly consolidated global supply chains, particularly in generics and antibiotics. Today, similar pressures are emerging in other segments, including biosimilars, while the EU's relative position in pharmaceutical innovation is arguably weakening. Around 55% of global API production is now concentrated in China and India, against 30% in the EU and 10% in the US.[2]

From an economic security perspective, three further concerns exist:

1. **Exposure to choke points controlled by third countries willing to exploit them.** Europe must limit its exposure and diversify away from core dependencies.

2. **Cascading effects due to upstream disruptions**, be they man-made (e.g. Strait of Hormuz) or natural (e.g. earthquakes). A substantive gap in knowledge of exposure areas remains, which must be closed to undertake appropriate preparatory actions.

3. **Technology leakage linked to deliberate use of export controls.** China is using export controls to entice companies to relocate to the country in exchange for lifting restrictions.

The pharmaceutical sector – including innovative as well as off-patent medicines – is often overlooked in economic security discussions due to the perception that other sectors face more acute or time-sensitive vulnerabilities. However, successive crises have created greater awareness about the fragility of concentrated supply chains and the importance of foresight and anticipation. Coupled with a growing understanding of global competitive pressures, the concept of the European preference has emerged as a complementary element of the EU toolbox.

ABOUT: EUROPEAN PREFERENCE

In this paper, European preference refers to an industrial policy approach prioritising resilience, with an emphasis on EU-based manufacturing, diversified supply chains, and trusted production networks, while ensuring compatibility with openness and international partnerships.

BACKGROUND

Navigating heightened global pressures

Europe is striving to preserve a position of strength between two different but very efficient models. On the one hand, China applies the same playbook as in other industries to the pharmaceutical sector: the Healthy China 2030 plan makes biomedicine and biomanufacturing top strategic priorities,[3] combining strategic planning, massive public funding, regulatory support and a large domestic market as a springboard for global expansion. Self-reliance is a core priority throughout Beijing's latest five-year plan, as are pharmaceutical supply chains to the country's economic security. In the meantime, the US is using tariffs and its market size to attract R&D, manufacturing and investment back home – in addition to its own fast-tracked FDA approval timelines, tax credits and self-preferencing in procurement.

While the pharmaceutical industry is one of the EU's principal remaining globally competitive sectors, with strong R&D and manufacturing and a deep scientific and clinical base, it needs to keep in mind the lessons of the steel, solar panel and electric vehicle industries. In these industries, Europe started from a position of strength, with technology, industrial capacity and global companies, but was systematically outcompeted in all three.

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Compared to the US and China, which are laser-focused on industrial policy, the EU's efforts appear lacklustre. On the supply side, the time for clinical trial approval used to be 160 days. The EU Biotech Act,[4] proposed in December 2025, would reduce clinical trial authorisation from 75 to 47 days. However, this ambition compares to China's goal of just 30 days for eligible drugs.[5] The European Medicines Agency's drug approval time is similarly down from 210 days to 180 thanks to the recent agreement on the reform of the General Pharmaceutical Legislation (GPL),[6] pending final adoption.

Europe has real strengths – large and predictable demand, world-class clinical research capacity and stable institutions – but these are often not used to their full potential. In addition, in EU healthcare expenditure is largely embedded within social healthcare

systems, where public payers dominate. As a result, pharmaceutical policies are heavily shaped by price pressures and cost-containment measures, creating an increasingly stringent operating environment for companies.[7] This distinction represents one of the key structural differences compared to other markets such as the US or China.

In this context, EU action has focused on the need to:

- Simplify and accelerate the regulatory framework through reform of the GPL and the Biotech Act;
- Unlock private capital, given that enormous savings and pension assets are not flowing into the pharmaceutical sector at sufficient scale;
- Use the single market, nearly non-existent in pharmaceuticals, more strategically, overcoming limitations resulting from the treaty-based division of competences.

The Critical Medicines Act (CMA),[8] on which co-legislators reached a provisional agreement in May 2026, may be seen as the first initiative to enshrine a type of European preference in the EU policy framework. It is designed as a strategic toolbox to enhance resilience,[9] address dependencies on third country imports, and ensure equitable access to treatment while maintaining European competitiveness. Throughout the file's negotiations, the Act evolved from a response to short-term shortages into an industrial policy tool. In parallel, the Commission proposed the Industrial Accelerator Act (IAA)[10] in March 2026, introducing 'Made in EU' procurement criteria across strategic sectors, with a further legislative proposal amending the Public Procurement Directive expected following stakeholder consultation.[11]

STATE OF PLAY

Operational resilience: converting principle into reality

While the increased focus on the pharmaceutical sector attests to its strategic importance, it is also one fraught with complexity. There are no one-size-fits-all solutions: strict localisation rules can clearly harm security, resilience, competitiveness and the potentially availability of pharmaceutical products. For products such as biosimilars and plasma-derived therapies, supply chains have unique characteristics. While in some cases, hundreds of providers make up the supply chain, in others, smaller but global supply networks themselves result from redundancy planning. As such, mandating a strict EU-preference approach in public procurement can in certain cases make supply more fragile[12] and risk harming supply chains proven to be reliable. In addition, if the threshold for EU manufacturing is set above required capacity, health systems may end up footing a higher bill than necessary.

The recent GPL reform already contained important elements for security of medicine supplies. Shortage prevention plans were introduced for prescription medicinal products, based on which pharmaceutical companies must notify any product withdrawal well in advance. Regulatory incentives encourage early applications for marketing authorisation in the EU and the conduct of multi-country clinical trials, so new therapies reach health systems sooner. Strong supply obligations were introduced for centrally authorised medicines: the marketing authorisation holder must now launch products in an early phase and maintain supply over time.

As part of the newly reached agreement on the CMA, the integration of resilience and security-of-supply criteria into public procurement of critical medicines will become mandatory, with resilience criteria taking precedence over price for contracts covering products on the Union list of critical medicines.[13] The co-legislators agreed to limit these provisions to vulnerable products on the Critical Medicines List, which will help focus those provisions on a clearly defined set of medicines where resilience concerns are most relevant. They also agreed to prioritise multi-winner tenders. For critical medicines with vulnerable supply chains due to concentrated dependency on third countries, contracting authorities may reward suppliers in proportion to the share of medicinal products and active substances they manufacture in the EU.

Diversification of supply, operationalised through multi-winner contracting, is itself a resilience instrument: it reduces single-source exposure, sustains a broader manufacturer base and lowers the probability that any one disruption cascades into a shortage – particularly in the off-patent segment. While these are important objectives, retaining flexibility and a margin for adjustment is essential in practice. In addition, the criteria should be broadened to capture all parts of the industry's investment bringing value and contributing to patient access, including sourcing raw materials and APIs, clinical trials, basic research, manufacturing and packaging, rather than APIs or a single component. An open-minded, 'made-with-Europe' approach focused on genuine value-generation is needed.

The pace of legislative processes raises a coordination risk. The CMA, Biotech Act, Public Procurement Directive and IAA each contain procurement-related provisions, drafted on distinct timelines and across different Commission services. The CMA in particular leaves significant discretion to member states in defining national programmes and how EU-preference criteria will be applied in practice. Absent effective coordination, inconsistent transposition into national law may risk exacerbating single market fragmentation for pharmaceuticals rather than overcoming it.

Resilience, societal and industrial, is a key driver behind the European preference drive. In the context of broader global tensions, concerns extend beyond security of supply, to the goal of building and enhancing strategic autonomy across technology and reducing reliance on foreign intellectual property. Supply security is a function of several interconnected factors:

a strong manufacturing base within the EU, diversity of production involving trusted international partners, and cost structures and market rules that enhance competitiveness. An imbalance in any of these areas creates significant risks and exposure.

In line with the principle of open economic security, narrow self-reliance may not be the most effective way of preparing for shocks or addressing vulnerabilities. Resilience criteria need to be defined holistically, reflecting how value creation emerges from different components, notably R&D. They must be granularly assessed, considering long-term effects. As testified by a September 2025 European Parliament resolution,[14] evaluation and data-driven approaches are essential to correctly defining the criteria for European preference in public procurement while complying with international commitments.

The Public Procurement Directive revision thus requires explicit alignment with the CMA. The Commission is expected to table a legislative proposal in Q3 2026, with strategic autonomy and 'Made in Europe' criteria among its stated objectives.[15] Without coordination, the EU risks layering two procurement regimes onto the same contracts: a horizontal one with general resilience criteria, and a sectoral CMA regime with mandatory provisions on the Critical Medicines List. The revision should clarify the respective roles of the Commission and member states in activating preference criteria, implementation mechanisms and oversight to ensure consistency. Failure to do so would push much of the operational discretion to national contracting authorities, with uneven application.

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INNOVATION AS A DURABLE DRIVER OF RESILIENCE

While current political momentum clearly points towards support for re-shoring production, structural reform must come first. Manufacturing capacity is not Europe's principal concern in the pharmaceutical sector, given that the EU exports most of its production. Support should therefore prioritise the upstream and access conditions on which manufacturing decisions depend, since manufacturing follows innovation and market access. Pharmaceutical companies invest in robust production capacity where innovation is developed, trials are conducted, products are launched rapidly and market access and value recognition are predictable and adequate.[16] Without improving capital availability and pricing reforms, prioritising localised production risks being a recipe for failure.

Long-term resilience is built upon the ability to secure a strong position at the frontier of innovation. The European life sciences ecosystems success can be measured through several critical indicators. The European Medicines Agency (EMA) should become the first or second global destination for marketing authorisation applications, and European healthcare systems should be the foremost location for innovation uptake. Equally important is the availability of strong Series A investment, necessary to sustain and scale a competitive biotech sector. Regulatory agility, cohesive governance and strategic financing are deeply interconnected drivers of a thriving European health innovation ecosystem.

The EU can use its regulatory framework, digital health and industrial instruments more forcefully as drivers of innovation-led resilience. The CMA's Strategic Projects designation, Life Sciences strategy,[17] IAA and Biotech Act provide a toolkit that links financial support, fast-tracked permits and access to the Strategic Technologies for Europe Platform.[18] The EMA's increasing focus on emerging breakthroughs – complemented by the Accelerating Clinical Trials initiative, with its endorsement of decentralised and adaptive trial models, support for multi-country clinical trials and the Europeanisation of health data – point to the possibility of a European pathway to innovation access, one that could also express an EU preference without resorting to protectionism.

PARTNERSHIPS IN EUROPEAN PREFERENCE

The EU benefits from a unique network of free trade agreements and trusted partners. Thorough and mutually balanced partnerships with built-in reciprocity mechanisms must be part of strengthening the sector's economic security. Diversification through agreements and enhanced regulatory alignment with partners, including Southeast Asia, Mercosur, Australia and Switzerland, could reduce single-point-of-failure risks. The CMA itself foresees this, authorising[19] the Commission to conclude arrangements with third countries, groups of third countries and international organisations to broaden the supply chain and reduce dependencies on single suppliers. In this area, the EU must be clear about terms of reference, so that industry understands what manufacturing footprint it may hold in a partner country, and that third countries understand what is expected, to benefit from strategic partnerships.

The agreement also explicitly subordinates procurement provisions to EU obligations under the WTO Agreement on Government Procurement and applicable free trade agreements. Maintaining this discipline matters: criteria that cannot demonstrate a genuine, evidence-based resilience rationale risk being characterised as *de facto* protectionism.

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Regarding preparedness for health emergencies, the Health Emergency Preparedness and Response Authority's (HERA) approach is based on open innovation and access – assuming that one cannot fight future threats with yesterday's defences. Health cooperation agreements are developed with like-minded third countries, while the pool of scientific excellence is global. Beyond emergency preparedness, several of HERA's working practices, notably joint procurement, R&D financing for medical countermeasures and structured engagement with industry consortia, have already generated transferable governance lessons. The EMA Steering Groups established under a 2022 Regulation,[20] most notably the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), offer a relevant model. Developed in crisis settings, they now coordinate vulnerability assessments for more than 200 active substances on the Union list of critical medicines under a methodology adopted in November 2025.[21] These mechanisms could help shape more structural, non-emergency resilience governance under the CMA and IAA.[22]

EMA's crisis-born steering groups – especially the MSSG – now assess vulnerabilities across 200+ critical medicines. Their model could guide long-term, non-emergency resilience under the CMA.

For certain threats such as Ebola, pandemic influenza and emerging infectious diseases, the most advanced technologies, vaccines or manufacturing capabilities may currently be found outside the EU. As such, HERA works closely with and procures from the EU as well as partner countries, including the UK and Australia.

RECOMMENDATIONS AND CONCLUSIONS

Four priorities follow from the analysis above:

- **Coordinate before layering.** The Commission and member states should prioritise coordination between legislative instruments and be aware of the risk of overlapping or potentially contradictory rules. Publication of implementation guidelines and timelines, in consultation with relevant stakeholders and coordinated between DG SANTE, EMA and national authorities, would reduce compliance fatigue and overlapping obligations across the GPL, CMA, IAA and Biotech Act. This would prevent the incoherence arising from 27 national transpositions of overlapping regimes, which could otherwise undermine the integrity of the single market.

- **Operationalise vulnerability assessments under the CMA.** The Critical Medicines Coordination Group, working with HERA and the MSSG, should conduct detailed, continuously updated supply-chain-level vulnerability assessments, building on the Critical Medicines Alliance methodology and available regulatory databases.[23] Given the concentration of the list across off-patent burden of manufacturer-led data collection, assessments should avoid creating parallel reporting obligations. Where preference provisions are invoked, the underlying assessment should be evidence-based, publicly documented and consistent with WTO Government Procurement Agreement obligations.

- **Strengthen supply diversity, not just EU localisation.** Multi-winner tenders should be the default for public procurement of medicines on the Critical Medicines List, with single-source contracts requiring explicit justification. This should be reflected in CMA implementation guidance and in the revised Public Procurement Directive to avoid concentrating supply in pursuit of EU production.

- **Address the growing disconnect between European resilience ambitions and national pharmaceutical policies.** While recent EU initiatives increasingly promote diversification and EU-based manufacturing, national pricing and reimbursement frameworks in many member states incentivise the opposite: growing clawbacks, lowest-cost and price-only procurement, offshoring and single-source dependency. Without stronger alignment between EU industrial policy objectives and national economic incentives, localisation requirements risk becoming economically unsustainable and difficult to operationalise.

In its pursuit of a European preference scheme, the EU should firstly clarify its goals. The decisive argument should not have to do with folding into a broader international trend, however inevitable that might seem, but with finding Europe's own path. Scientific and technological prowess and innovation are where real value creation lies. They should be prioritised.

European preference is not a silver bullet. The EU should implement European preference with caution to avoid inviting new risks while addressing others. A holistic and qualitative 'made with Europe' approach should be prioritised, encompassing not only manufacturing location, but also R&D and clinical trials, particularly across borders.

The EU is going through a period of soul-searching, trying to square its WTO commitments, single market principles, industrial policy and realpolitik. Mixed signals are understandable, but more clarity is needed with respect to how vulnerability assessments will be carried out under the CMA and IAA, and what role HERA will play in procurement and EU localisation criteria.

Speed is of the essence. The measures under discussion today will deliver tangible results in, at best, three to four years. Meanwhile, China can scale up targeted production far faster than anticipated, with consequences felt in Europe within 12 months.[24]

Proper investment is equally critical: maintaining Europe's strength in pharmaceuticals requires a major increase in funding for research and innovation. Finally, while European preference criteria can help, they must not distract from the deeper structural choices that the pharmaceutical sector now faces.

This Policy Brief draws on the discussions from a European Policy Centre Round Table, held in Brussels on 22 April 2026. The authors are grateful to the participants of the Round Table for their invaluable insights.

The project is pursued in collaboration with Amgen, CSL and Viatris.

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